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Cardiac implantable electronic devices procedures and their recipients characteristic during COVID-19 pandemic: 3.8 million population analysis

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Abstract

Background: *Coronavirus disease 2019 (COVID-19) pandemic disorganised healthcare systems and has caused a reduction in the number of hospitalizations and procedures. Cardiac implantable electronic device (CIED) procedure rates and clinical characteristics of their recipients were compared in corresponding weeks of 2019 and 2020 were analyzed.*

Methods: *The database of the National Health Fund (NHF) in Poland was retrospectively analyzed. 3206 patients who underwent CIED implantation in the Silesia — a region in Southern Poland comprising an adult population of 3.8 million between 12th and 31st week of 2020. Patients were classified into groups: the recipient of an implantable cardioverter-defibrillator or cardiac resynchronization therapy group (ICD/CRT) or pacemaker group (PM).*

Results: *During the pandemic a reduction of 39.38% of implantations was observed compared to the same period in 2019 (1210 vs. 1996 patients) and had impacted both groups. Two phases lasting 10 weeks each could be distinguished: total lockdown (maximal reduction) and the recovery phase with growing numbers of procedures. Patient baseline characteristics (sex, age, comorbidities) who were implanted during the COVID-19 pandemic did not differ from the 2019 period. The rate of peri-procedural mortality was also similar.*

Conclusions: *During COVID-19 pandemic period a reduction in CIED implantations of all types was observed. Despite the decreased number of performed CIED implants, no differences in baseline patient characteristics were observed.* (Cardiol J 2022; 29, 1: 27–32)

Key words: COVID-19, cardiac implantable electronic devices, pacemakers, implantable cardioverter-defibrillator, cardiac resynchronization therapy, pandemic

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Introduction

The pandemic caused by severe adult respiratory system coronavirus-2 (SARS-CoV-2 [COVID-19]) forced major changes of healthcare systems worldwide. Numerous elective admissions were revoked or postponed and in-hospital treatment focused mainly on acute cases, substantial resources were used to fight the infection. This issue also concerns the patients planned for cardiac implantable electronic devices (CIED) procedures and may affect a patient's profile. Governmental regulators, insurance companies, as well as national and international professional societies published several rules or recommendations which should be or are advised to be implemented during the pandemic [1, 2]. In Poland the regulator of the National Health Fund (NHF) on March 13th, 2020, as well as the Heart Rhythm Association of Polish Cardiac Society (March 26th, 2020) strongly advised performing only urgent procedures: implantation of a pacemaker (PM) due to the second- or third-degree atrioventricular block, placement of implantable cardioverter-defibrillator (ICD) in the secondary prevention of sudden cardiac death, exchange of pacing systems and ICDs due to battery depletion or damage to the leads, removal of pacing/defibrillation systems because of infections and ablations of incessant and resistant to other forms of treatment life-threatening supraventricular arrhythmias as well as dangerous recurrent chronic ventricular arrhythmias [2]. In parallel, low symptomatic patients even classified in the abovementioned categories were afraid to be hospitalized even in a non-COVID-19 hospital so they will to postpone the procedure.

The aim of the analysis was to evaluate the changes in implantation rates and clinical characteristics of CIED candidates before and during the COVID-19 pandemic.

Methods

A retrospective analysis with the use of an NHF database, the only public insurance company in Poland, was performed. Data were collected from the Silesian Cardiovascular Database (SILCARD), which contains records from 310 hospitals located in Silesia, a large, urbanized region in Southern Poland populated with 3.8 million adults (a total of 4.5 million — 11.8% of Poland's population). The SILCARD database is obtained from the NHF and contains raw, anonymized data: the principal diagnosis with up to three comorbidities, type of implanted CIED, administrative and epidemiological pieces of information. Silesia contains a well-developed hospital network, with two tertiary cardiology teaching hospitals and 22 implantation laboratories (Fig. 1). General information on SILCARD was previously reported [3]. In short, the SILCARD database enrolled all consecutive Silesian adult patients hospitalized in cardiology and cardiac surgery units for cardiovascular disease (CVD). Patients living outside of Silesia and patients younger than 18 years at the time of admission were excluded. The hospitals are reporting a principal diagnosis with up to three comorbidities as defined by the 10th revision of the International Classification of Disease (ICD-10) classification for every hospitalization and medical procedure codes (ICD-9). CVD was defined as any "I" code according to the ICD-10. For implantation identification, code Z45.0 was used in parallel with procedure code for the first implantation of the appropriate device. All vulnerable data were anonymized. The local Ethics Committee approved the use of the SILCARD registry. Based on the information received from the NHF, data from pre-specified periods were analyzed. The three periods were defined as the following: pre-pandemic (2nd – 11th week), lockdown (12th – 21st week), stepdown (22nd – 31st). The ICD-10 codes have been reported to the NHF since the beginning of the registry's existence to current hospitalizations. Because of the type of investigation, consent from patients was waived.

Patient analysis

De-novo, device implantations of PM, ICD and cardiac resynchronization therapy (CRT) devices were analyzed, but the urgency of the procedure (urgent or elective) was not differentiated. Generator replacements were excluded from the analysis, because these patients were classified as urgent cases and the regulator did not recommend postponing procedures. Patients who received devices were classified into two groups according to the device type: ICD/CRT or PM.

Time analysis

Firstly, a direct comparison of pandemic phase from 12th to 31st week of 2020 was compared with the same phase in 2019. Secondly, after examining weekly trends, the pandemic phase was broken into two: complete lockdown (weeks 12th – 21st) and step-down, recovery phase (weeks 22nd – 31st) and compared them not only to corresponding weeks in 2019 but also to same length in the pre-pandemic phase (2nd – 11th week of 2020).

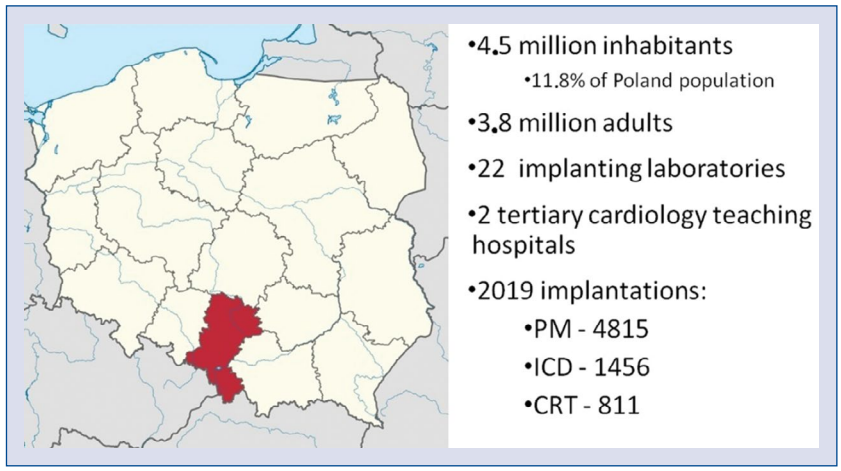

Figure 1. Silesia voivodeship population and 2019 implantations. CRT — cardiac resynchronization therapy; ICD — implantable cardioverter-defibrillator; PM — pacemaker.

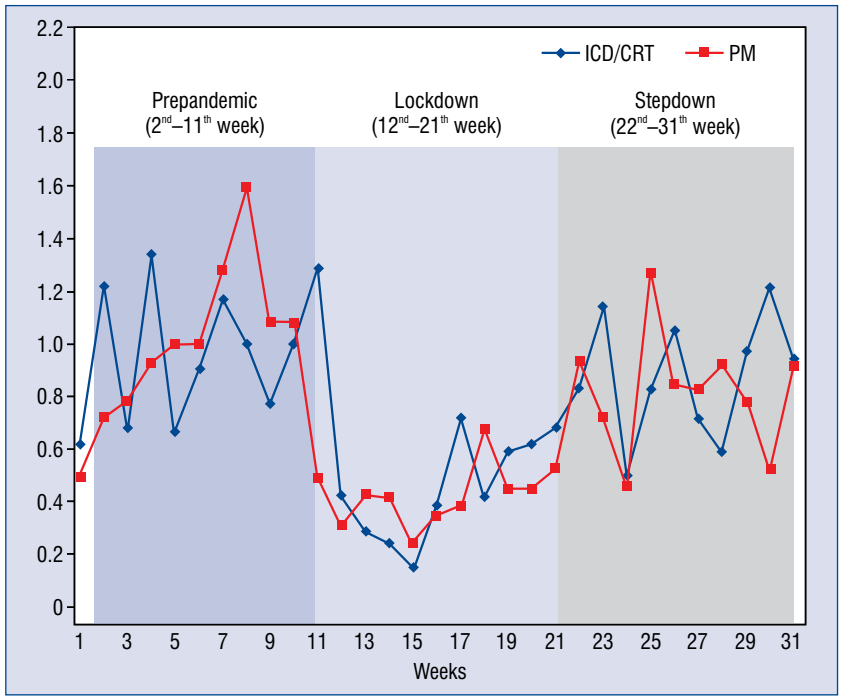

Figure 2. Implantation rate of implantable cardioverter-defibrillator/cardiac resynchronization therapy (ICD/CRT) and pacemaker (PM) as a ratio of 2020/2019 numbers for consecutive weeks 1 to 31.

Statistical analysis

Continuous variables are presented as the median with interquartile range due to non-normal distribution. Categorical variables were expressed as frequencies and percentages. Statistical analysis was performed with the χ^2 test or U Mann-Whitney test as appropriate. A two-sided p-value < 0.05 was considered significant. The SAS software, version 9.4 (SAS Institute Inc., Gary, NC) was used for all calculations.

Results

Overall, data from patients who underwent CIED implantation from the 12th to 31st week were analyzed. The number of implantation procedures during the COVID-19 period decreased by 39.38% compared to the same period in 2019 (1210 vs. 1996 patients). The reduction concerned both types of devices: ICD/CRT group: decrease of 35.81% (423 vs. 659); PM group: decrease of 41.14% (787 vs. 1337) (Fig. 2).

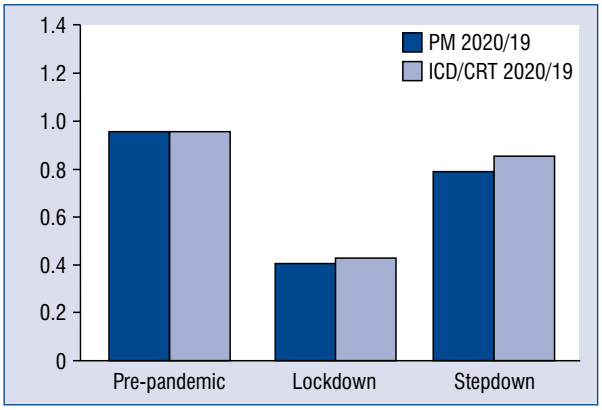

Figure 3. Comparison of implantation rates of pacemaker (PM) and implantable cardioverter-defibrillator/cardiac resynchronization therapy (ICD/CRT) as a ratio of 2020 and 2019 numbers for the three 10-week periods: pre-pandemic (2nd–11th week), lockdown (12th–21st week) and stepdown (22nd–31st).

After the end of the first wave of the pandemic (complete lockdown) since June 2020, the number of implantations gradually increased, and almost reached pre-pandemic levels. The most noteworthy drop was between 12th to 21st week of 2020: all patients — a decrease of 54.74% (506 vs. 1118); ICD/CRT group — a decrease of 53.95% (163 vs. 354); in PM group — a decrease of 55.1% (343 vs. 764). Pre-pandemic data of 2020 (2nd to 11th week) corresponded with 2019 numbers (ICD/CRT 347 vs. 364, PM 688 vs. 719). The data from the final 10-week period — partial recovery (22nd to 31st week) showed a higher number of implantations: greater in ICD/CRT (286 vs. 334), also important, but was less pronounced in PM group (495 vs. 626) (Fig. 3).

The clinical characteristics of the CIED recipients from 2019 and 2020 were similar in both groups (Tables 1, 2). No significant differences were found in age, sex, symptoms, heart disease and comorbidities. Moreover, the in-hospital mortality related to implantation procedures was also similar.

Discussion

In Poland a national lockdown was implemented on March, 14th, 2020. Worldwide, the COVID-19 pandemic decreased the number of elective and urgent cardiac procedures. The decline was expressed especially in the first weeks after the lockdown was introduced. In Italy, in the Veneto region, a significant decrease in the number of urgent PM implantations was observed during the 6 weeks after the COVID-19 outbreak [4]. In Peru, in the national reference hospital, the largest in the country, a reduction in the de-novo PM implant was 73% (95% confidence interval [CI] 33–113; $p < 0.001$), observed during the COVID-19 pandemic [5]. Marini et al. [6] showed that the clinical characteristics of urgent CIED recipients remained the same despite the COVID pandemic. Results of present analysis are in line with these

Table 1. Clinical characteristics of implantable cardioverter-defibrillator/cardiac resynchronization therapy recipients in the compared periods of 2019 and 2020.

	Year		P
	2019	2020	
Number of patients	659	432	
Age, median (Q1, Q3)	68.9 (62; 75)	68.2 (61; 74)	0.425*
Male gender	521 (79.1%)	336 (79.4%)	0.939
Hypertension	401 (60.8%)	260 (61.5%)	0.848
Diabetes	175 (26.6%)	115 (27.2%)	0.833
Previous PCI	359 (54.5%)	219 (51.8%)	0.417
Previous CABG	74 (11.2%)	65 (15.4%)	0.051
Previous MI	269 (40.8%)	173 (40.9%)	1.000
Chronic kidney disease	49 (7.4%)	21 (4.9%)	0.128
History of AF	208 (31.6%)	143 (33.8%)	0.464
Peri-procedural mortality	2	1	0.838

*U Mann-Whitney test, the remaining χ^2 test; AF — atrial fibrillation or flutter; CABG — coronary artery bypass grafting; MI — myocardial infarction; PCI — percutaneous coronary intervention

Table 2. Clinical characteristics of pacemaker recipients in compared periods of 2019 and 2020.

	Year		P
	2019	2020	
Number of patients	1337	787	
Age, median (Q1, Q3)	77.2 (70; 83)	77.8 (71; 83)	0.209*
Male gender	653 (48.8%)	381 (48.4%)	0.584
Hypertension	709 (53.0%)	433 (55.0%)	0.392
Diabetes	262 (19.6%)	147 (18.7%)	0.649
Previous PCI	244 (18.2%)	149 (18.9%)	0.729
Previous CABG	75 (5.6%)	35 (4.4%)	0.266
Previous MI	160 (12.0%)	101 (12.8%)	0.584
Chronic kidney disease	74 (5.5%)	42 (5.3%)	0.921
History of AF	387 (28.9%)	228 (29.0%)	1.000
Peri-procedural mortality	5 (0.4%)	9 (1.1%)	0.034
Yates corr. 0.066			

*U Mann-Whitney test, the remaining χ^2 test; AF — atrial fibrillation or flutter; CABG — coronary artery bypass grafting; MI — myocardial infarction; PCI — percutaneous coronary intervention

observations. There are several explanations for the decrease in the number of CIED implantations. First, the fear of getting the COVID-19 infection unmotivated those looking for medical attention even for severe symptoms. The fear also leads to postponing previously planned procedures in low symptomatic cases. This fear has been reported in a study of psychological responses to emerging outbreaks of infectious diseases [7] and reduced admissions for acute coronary syndromes and reduction in primary percutaneous coronary interventions [8]. The German Helios network study revealed a deficit of hospitalizations due to several categories of CVD during the pandemic [9].

Another reason could be transitory impeded access to medical healthcare. It is not only about hospital emergency departments, where the most symptomatic patients come. The system may have missed asymptomatic or mildly symptomatic patients who had limited access to outpatient clinics and professional societies published several documents on how to deal with different categories of patients during the pandemic, advising to postpone elective cases [1, 2]. The Italian Society of Arrhythmias and Cardiac Pacing survey revealed a significant reduction of procedures including not only urgent PMs but also of ICD implantations for primary, as well as secondary prevention in a majority of hospitals [10].

It is worth emphasizing that in the present analyses the total number of implanted generators, not only urgent cases were examined. In the first weeks after the national lockdown was introduced, the decline of implantations was very visible. Probably, during this period, only urgent, life-saving procedures were performed. In the following weeks, when both patients and medical healthcare got used to pandemic conditions (e.g., nosocomial procedures for testing, isolation and disinfection), progressive recuperation was observed, and elective implantations have been reintroduced. Interestingly, it seems that ICD/CRT implants number grew faster than PM. Finally, the in-hospital mortality related to implantations procedures was comparable. At the level of statistical significance, the peri-procedural death was higher during pacemaker implantations during the COVID-19 period. It is conceivable that higher mortality resulted from more severe baseline condition of patients who delayed admission to hospital and possible COVID-19 co infection.

Limitations of the study

Lack of differentiation between types of hospital. Types of procedure and peri-procedural complications may vary between COVID-19 and non-COVID-19 hospitals as well as between tertiary teaching hospitals vs. implantation laboratories.

Cardiac implantable electronic device replacement procedures were excluded from the analysis.

Lack of differentiation between urgent and elective procedures.

Data about procedures performed in COVID-19 patients are not available.

Conclusions

During the COVID-19 pandemic period a reduction in CIED implantation of all types was observed. Despite the decreased number of performed CIED implants, no differences in baseline patient characteristics were observed.

Conflict of interest: None declared

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