Patients with heart failure and an implanted cardioverter--defibrillator during the coronavirus disease 2019 pandemic: insights from a multicenter registry in Poland

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INTRODUCTION

The outbreak of the coronavirus disease 2019 (COVID-19) has spread into a pandemic affecting more than 76 million people worldwide and causing nearly 1.7 million deaths so far and has become a disaster for healthcare systems around the world. Moreover, similar to other pandemics of the past, it is forcing preponderant alterations in many fields of medicine.

According to current practice guidelines, a significant portion of patients with heart failure (HF) receive implantable cardioverter-defibrillators (ICDs) with or without cardiac resynchronization therapy (CRTs) due to well-evidenced clinical benefits which include a long-term improvement of prognosis [1]. In patients hospitalized for COVID-19, the presence of HF is a powerful independent predictor of mortality and in-hospital complications [2].

While a follow-up is a strongly recommended element of care in patients with HF and ICD/CRT, including in many cases an in-person visit for clinical and technical evaluation of the implanted device, the pandemic has limited patient's contact with the medical staff in order to obtain rigorous isolation and reducing a human-to-human possible virus transmission.

In accordance with the Heart Rhythm Society Guidance, direct medical visits should be limited as much as possible in favor of the use of telehealth solutions [3]. Furthermore, teleconsultations have been approved by the Polish National Health Fund and implemented countrywide. However, prior to the spread of the pandemic, the use of telemedical services for patients with HF and ICD/CRTs was not widely implemented in everyday clinical practice.

Although over the last years, the introduction of remote monitoring (RM) of ICD/CRTs has significantly improved the prognosis in HF-patients [4] and its role may be even more significant in the current difficult reality, it is well known that RM can be clinically effective when RM care is based on the experienced medical staff. This requires logistic solutions, such as developing a model of alert-triggered clinical reactions, which requires ample time to achieve [5]. Moreover, mainly due to reimbursement issues, the use of RM in Poland is restricted. Besides some initial data regarding their clinical efficacy [6], teleconsultations, as the only pattern of supervision in patients with HF and ICD/CRT to date, have not been widely examined. Therefore, there are some legitimate concerns about the safety of such a model of

supervision, especially regarding potentially lethal and clinically silent events (arrhythmic events, lead integrity defects, premature battery depletion, or device-related infections).

Taking into consideration the above-mentioned issues, the purpose of the present study was to analyze the landscape of follow-up in patients with HF and implanted ICD/CRTs during the first 2 months of the outbreak of COVID-19 in Poland. We strongly believe that the study may be a cornerstone for assessing the impact of the change in supervision related to the pandemic on long-term clinical outcomes in patients with HF and ICD/CRTs in the future.

METHODS

We performed an analysis in consecutive patients with HF and implanted ICD/CRTs included in the multicenter registry from 6 tertiary, academic, high-volume cardiovascular hospitals in Poland. The study compared follow-up routines from the 2-month observation period starting with the beginning of the COVID-19 epidemic in Poland (March 14th, 2020) and the corresponding period of 2019. We investigated baseline characteristics, types of visits, ICD/CRT interventions, arrhythmic events, and clinical interventions. The percentage of individual forms of visits was calculated in relation to the number of all visits in the observation periods. At the same time, the number of interventions is presented in relation to the overall number of patients included in the analysed groups. The study was approved by an appropriate institutional review board and — given the retrospective nature of the analysis — a written informed consent to participate in the study was not required.

Statistical analysis

The qualitative variables were expressed as absolute number and percentage and were analyzed with the χ^2 test (where numbers were anticipated to be less than 5, Yates' correction for continuity was implemented). The distribution of continuous variables was verified using the Shapiro–Wilk test. Continuous variables were expressed as median and interquartile range (IQR). The significance of differences between median values was tested with the U-Mann–Whitney test. A *P* value of less than 0.05 was regarded as significant. Statistical analysis was performed using SPSS software version 25.0 (IBM Corp., Armonk, New York, United States).

RESULTS AND DISCUSSION

We recorded a reduction (16.5%) in the number of patients included in the study and in the control period (1259 and 1508, respectively), which provided a basis for the analysis. The baseline clinical and device characteristics were similar between the study groups (Table 1). During the coronavirus pandemic, a landscape shift in the follow-up care was observed, with a 16.8% reduction in all follow-up visits (1343 vs 1615), a higher rate of cancelled scheduled visits (15.8% vs 0.7%; *P* <0.001), scheduled telephone visits (66.7% vs 0%; *P* <0.001), and scheduled visits using only remote monitoring (14.4% vs 0%; *P* <0.001), as well as a lower rate of scheduled outpatients visits (20.1% vs 87.6%; *P* <0.001).

Despite the fact that significantly more patients with ICD/CRTs were supervised remotely (RM or teleconsultations), the rate of diagnosed appropriate ICD interventions (anti-tachycardia pacing or shock) due to life-threatening ventricular arrhythmias and the detection of *de-novo* atrial fibrillation remained similar in both groups (5.1% vs 4.4%; *P* = 0.43 and 2.62% vs 2.4%; *P* = 0.7, respectively). Equally, a proportion of diagnosed ICD/CRT technical dysfunctions were comparable in both analyzed time periods (3.5% vs 2.65%; *P* = 0.7). However, a significantly lower rate of inappropriate ICD interventions, and any arrhythmia detections and clinical reactions, mainly due to a pharmacotherapy change, were recorded in 2020 (Table 1). Possible reasons for this appear to include the organizational changes in the health care system and the greater level of stress among patients [7, 8]. However, which is noteworthy, this was not related to urgent or scheduled hospitalization recommendations (Table 1).

The study shows a significant change in the rate and types of follow-up visits, inappropriate ICD interventions, any arrhythmia findings, and clinical reactions in patients with HF and implanted with ICD/CRTs during the first 2 months of the COVID-19 pandemic in 6 high-volume cardiovascular centers in Poland. It is possible that the impact, particularly on long-term clinical outcomes, requires further evaluation.

The study has been a retrospective analysis and it involves all the limitations related thereto.

Article information

Conflict of interest: MT received consulting fees from Abbott, Biotronik, Boston Scientific. MS received consulting fees from Abbott, Boston Scientific, Biotronik, Medtronic and Zoll. Other authors declare no conflict of interest.

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Table 1. A comparison of baseline and device characteristics, type of visits, and clinically important interventions in patients with heart failure and implantable cardioverter-defibrillators (with or without resynchronization). The study period is defined as the time between the state of epidemic introduced by the Polish government (March 14, 2020) and May 14, 2020. The control period was from March 14, 2019 to May 14, 2019

Variable	Study period	Control period	*P* value
Patients	**1259**	**1508**	
Baseline characteristics			
Male	1003 (79.7)	1185 (78.6)	0.81
Age, years, median (IQR)	68 (15)	68 (15)	0.92
Ischemic aetiology	827 (65.7)	939 (62.3)	0.71
Implantation due to secondary prevention of SCD	189 (15)	256 (17)	0.61
RM	475 (37.7)	525 (34.8)	0.64
Device type			0.92
Single chamber ICD	464 (36.9)	558 (37.0)	
Dual chamber ICD	326 (25.9)	404 (26.8)	
Subcutaneous ICD	1 (0.1)	3 (0.2)	
CRT	467 (37.1)	543 (36)	
Device manufacturers			0.03
Abbott/St. Jude	244 (19.4)	332 (22)	
Biotronik	235 (18.7)	302 (20)	
Boston	410 (32.6)	398 (26.4)	
Medtronic	369 (29.3)	476 (31.6)	
Follow-up visits			
All follow-up visits	1343	1615	
Cancelled scheduled visits[a]	212 (15.8)	11 (0.7)	<0.001
Scheduled outpatient visits[a]	270 (20.1)	1415 (87.6)	<0.001
Scheduled telephone visits[a]	896 (66.7)	0 (0)	
Scheduled visits using only RM[a]	194 (14.4)	0 (0)	<0.001
Unscheduled outpatient visits[a]	35 (2.6)	19 (1.2)	0.02
Unscheduled telephone visits[a]	11 (0.8)	0 (0)	0.001
Unscheduled visits triggered by patient or alert using only RM[a]	118 (8.8)	144 (8.9)	0.91
Appropriate ICD intervention[b]	64 (5.1)	67 (4.4)	0.43
VT	59 (4.7)	63 (4.2)	0.35
ATP during VT	55 (4.4)	56 (3.7)	0.65
Shock during VT	15 (1.2)	19 (1.3)	0.46
VF	12 (0.9)	17 (1.1)	0.42
Shock during VF	12 (0.9)	16 (1.1)	0.25
Electrical storm	9 (0.7)	5 (0.3)	0.42
Inappropriate ICD intervention[b]	12 (1.0)	24 (1.6)	0.03
AF *de-novo* episode[b]	33 (2.6)	36 (2.4)	0.72
Any arrhythmia[b]	107 (8.4)	201(13.3)	<0.001
ICD/CRT dysfunction[b]	44 (3.5)	40 (2.7)	0.70
Any clinical reaction[b,c]	206 (16.4)	321 (21.3)	<0.001
Phone contact	111 (8.8)	104 (6.9)	0.57
Pharmacotherapy change	82 (6.5)	137 (9.1)	<0.001
Urgent hospitalization	41 (3.2)	47 (3.1)	0.52
Scheduled hospitalization	23 (1.8)	30 (2.0)	0.33

Data are presented as the number (percentage) of patients unless otherwise indicated.
[a]Percent of all visits in the analyzed period. [b]Percent of all patients included in the analyzed period. [c]Due to clinical and/or arrhythmic event.
Abbreviations: AF, atrial fibrillation; ATP, anti-tachycardia pacing; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; IQR, interquartile range RM, remote monitoring; SCD, sudden cardiac death; VT, ventricular tachycardia; VF, ventricular fibrillation

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