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Patients with heart failure and an implanted cardioverter-defibrillator during the COVID-19 pandemic: insights from a multicentre registry in Poland

Short title: Patients with a cardioverter-defibrillator during the pandemic

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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 favour 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 every day 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 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 analyse the landscape of follow-up in patients with HF and implanted ICD/CRTs
during the first two 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 multicentre registry from six tertiary, academic, high-volume cardiovascular
hospitals in Poland. The study compared follow-up routines from the two-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 reactions. The percentage of
individual forms of visits was calculated in relation to the number of all visits in the observed
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 $\chi^2$ 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 (ATP 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 analysed 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 two months of the COVID-19 pandemic in six high-volume cardiovascular centres in Poland. It’s possible impact, particularly on long-term clinical outcomes, requires a further evaluation.

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

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

\(^a\)% of all visits in the analysed period

\(^b\)% of all patients included in the analysed period

\(^c\)Due to clinical and/or arrhythmic event

AF denotes atrial fibrillation

ATP denotes anti-tachycardia pacing

CRT denotes cardiac resynchronisation therapy

ICD denotes implantable cardioverter-defibrillator

RM denotes remote monitoring

VT denotes ventricular tachycardia

VF denotes ventricular fibrillation