Implementation of remote monitoring in patients implanted with T-ICD and S-ICD involved in a recall campaign: An excellent tool with insufficient availability

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INTRODUCTION

In March 2021, Biotronik released a notice informing about the possibility of premature battery depletion in implantable cardioverters-defibrillators (ICDs) and cardiac resynchronization therapy devices (CRT-D). According to the information provided by the manufacturer, the potential fault could apply to as many as 0.1% of devices implanted since 2013. The manufacturer did not recommend routine replacement of all potentially affected devices. However, it was suggested that these patients should be remotely monitored for early detection of premature battery depletion. A similar message regarding the premature depletion of batteries in subcutaneous cardioverter-defibrillators (S-ICDs) was published by Boston Scientific in December 2020. In addition, the message concerned the possibility of an unexpected failure of the subcutaneous defibrillation lead.

The purpose of this retrospective, single-center, observational study was to evaluate the results of a service campaign carried out at our department in patients with ICDs manufactured by Biotronik and Boston Scientific. As part of the service campaign, patients with devices susceptible to premature depletion of the power supply system (Biotronik and Boston Scientific) and additionally patients with EMBLEM S-ICD subcutaneous lead (Model 3501) with increased risk of fracture were invited for an enrollment visit and then included in the remote monitoring (RM) system.

METHODS

This retrospective study included patients with transvenous ICDs (T-ICDs), CRT-Ds, and S-ICDs identified as potentially susceptible to premature battery depletion or lead failure. Devices were implanted in the Department of Cardiology and Electrotherapy, Medical University of Gdańsk, from 2014 to 2020. Patients were invited via telecommunication or letter to an enrollment visit to include them in the remote monitoring group. Patients with cardiac implantable electronic devices (CIEDs) manufactured by Biotronik were monitored using the BIOTRONIK Home Monitoring® system, and patients with Boston Scientific devices were monitored with the LATITUDE™ NXT Remote Monitoring System. The follow-up period lasted from the enrollment visit to December 31, 2022; however, remote monitoring has continued after this date. The study endpoints were: (1) detection of premature battery depletion; (2) detection of damage to the S-ICD lead that meets the recall criteria; (3) replacement of the device covered by the recall campaign; (4) death of the patient.

Statistical analysis

Demographic data and clinical parameters of patients were included in the statistical analysis. Continuous variables were expressed as mean (standard deviation [SD]) if normally distributed. In the case of continuous variables, normal distribution was tested using the one-sample Kolmogorov-Smirnov test.

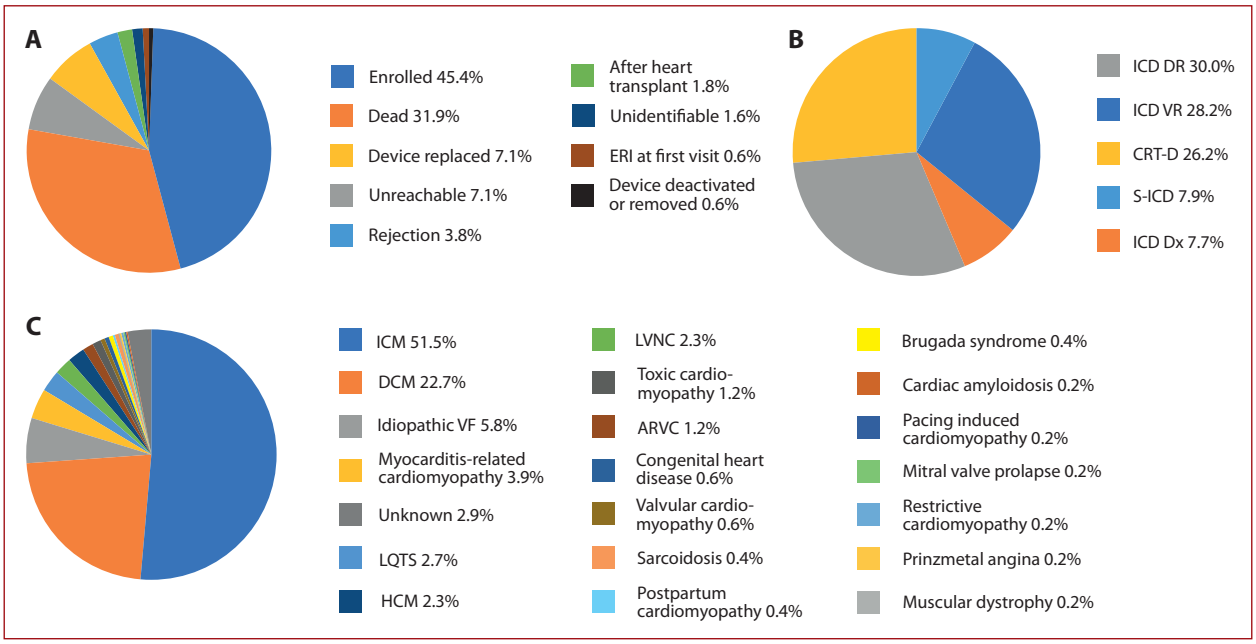

Figure 1. Characteristics of the study group. **A**. Results of enrollment visit. **B.** Types of implanted devices. **C.** Specific indications for the implantation of an ICD

Abbreviations: ARVC, arrhythmogenic right ventricular cardiomyopathy; CRT-D, cardiac resynchronization therapy-defibrillator; DCM, dilated cardiomyopathy; ERI, elective replacement indicator; HCM, hypertrophic cardiomyopathy; ICD DR, implantable cardioverter-defibrillator dual-chamber; ICD Dx, implantable cardioverter-defibrillator single-chamber with Biotronik Dx lead; ICD VR, implantable cardioverter-defibrillator single-chamber; ICM, ischemic cardiomyopathy; LQTS, long QT syndrome; LVNC, left ventricular non-compaction cardiomyopathy; S-ICD, subcutaneous implantable cardioverter-defibrillator; T-ICD, transvenous implantable cardioverter-defibrillator; VF, ventricular fibrillation

Categorical data were expressed as numbers and percentages. Data were analyzed with the use of STATISTICA 13 software. The study was approved by the bioethics committee (no. NKBBN/647/2022).

RESULTS AND DISCUSSION

Four hundred and seventy-four Biotronik devices and 41 Boston Scientific leads and devices have been identified as potentially threatened by dysfunction. These devices were implanted in 504 patients. In 98.4% of cases, it was possible to identify the patients by serial numbers of the device. The remaining 1.6% of devices were not identifiable most likely due to a mistake in the manual recording of serial numbers on the part of the hospital or the supplier. It is highly probable that they have not been implanted. One hundred and sixty-one patients (31.9%) died and 229 patients (45.4%) were eventually included in RM. Detailed characteristics of the recall results are presented in Figure 1A. The mean (SD) age of the identified patients was 68 (15) years. Patients with dual-chamber transvenous systems predominated (n = 151, 30.0%); detailed information is provided in Figure 1B. More than one-third (35.2%) of patients had an ICD implanted for secondary prevention of sudden cardiac arrest (SCA). In 85.5% of cases, patients suffered from chronic heart failure, with heart failure with reduced ejection fraction being the most common type (91.4%), followed by heart failure with mid-range ejection fraction (6.7%), and heart failure with preserved ejection fraction (1.9%). Mean (SD) left ventricular ejection fraction (LVEF) was 32 (12)%. The underlying etiology determining the need for ICD implantation was ischemic cardiomyopathy (51.5%) and dilated cardiomyopathy (22.7%). All etiologies are shown in Figure 1C. The average (SD) follow-up time in remote monitoring was 190 (64) days. At the time of the enrollment visit, 3 transvenous devices required replacement due to battery depletion. During the follow-up time, considering the entire study group, an indicator for elective replacement because of premature battery depletion was found in 5 transvenous devices. Dysfunction of subcutaneous ICD leads associated with the recall campaign was found in 2 cases (noises with inappropriate interventions). All patients with premature battery depletion or subcutaneous lead dysfunction were primary prevention ICD patients. Remote monitoring findings during follow-up are included in Supplementary materials, *Figures S1* and *S2*. In 1 case, T-ICD parameters were restored to default settings due to interference with the electromagnetic field. In 1 case, the RM device was found to be defective and was subsequently replaced.

It is crucial to determine the optimal management of patients with potentially defective CIEDs. In most cases, close monitoring (for instance, RM) will suffice, while some patient groups — pacemaker-dependent and those requiring secondary prevention of SCA — may benefit from more aggressive strategies. However, it should be noted that every, also prophylactic, replacement of the pulse generator or leads may carry a 2.5% risk of serious complications [1, 2]. Recalls and the resultant negative publicity may im-

pact ICD utilization. After the recall of the Medtronic Fidelis leads in 2007, the average monthly number of implants in the United States was modestly lower [3].

Taking into account 3 patients diagnosed with battery depletion on the RM enrollment visit and further 5 cases identified during follow-up, this complication was finally diagnosed in 3.5% of patients. This is a lower percentage than suggested by other authors (4.8%), which may be due to a shorter follow-up time (6 vs. 8 months) [4]. Data from the extended ELISIR experience (Experience from the Long-term Italian S-ICD registry) reported premature unanticipated device battery depletion in 2.2% of patients and lead fracture in 0.3%, which is in line with the expected rates reported by Boston Scientific [5].

RM allows optimal recall management and a rapid diagnosis of device or lead failure, without the need for additional in-office visits during which device interrogation and management are time-consuming [6, 7]. Importantly, RM enables not only the detection of dysfunction to the pulse generator and leads, but also indirect assessment of patients' clinical condition and, for instance, early detection of exacerbation of heart failure [8,9]. Unfortunately, too few of Poland's centers use RM of patients with CIEDs. Basic barriers to its wider implementation are concerns about additional workload and lack of RM reimbursement [10]. Fortunately, the National Health Fund has recently made declarations that the situation is to be changed in the near future — for which both we and patients are impatiently waiting. The main limitation of the study is the relatively short RM follow-up time. Monitoring is continued.

CONCLUSIONS

Although the rate of premature battery depletion in patients included in the recall is not high, patients with ICD devices — especially those with an ICD implanted for secondary prevention of SCA — should be closely monitored due to potentially life-threatening consequences of the device failure. Our study has confirmed the effectiveness of modern RM methods in this field.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

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