SHORT COMMUNICATION

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

Maciej Kempa¹, Grzegorz Sławiński¹, ², Piotr Zieleniewicz¹, Łukasz Dziurkowski¹, Elżbieta Wabich¹, Szymon Budrejko¹, Agnieszka Zienciuk-Krajka¹, Ludmiła Daniłowicz-Szymanowicz¹

¹Department of Cardiology and Electrotherapy, Medical University of Gdańsk, Gdańsk, Poland
²Club 30, Polish Cardiac Society, Poland

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.
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.

Recalls and the resultant negative publicity may im-