Safety issues in selected patients implanted with Boston Scientific EMBLEM subcutaneous cardioverter defibrillator systems

To the editor We strongly believe an important information has to be shared upon the manufacturer's information included in the urgent field safety notice released in English and Polish in December 2020[1,2] on the risk of: 1) premature depletion of the battery caused by malfunction of a low voltage capacitor, 2) occurrence of electrical overstress immediately after the delivery of high voltage therapy, and 3) electrode fracture that may occur in selected subcutaneous cardioverter defibrillators (S-ICD) by Boston Scientific. The Working Group appointed by the national consultant in cardiology and the board of the Heart Rhythm Section of the Polish Cardiac Society immediately prepared recommendations on the conduct in patients with such devices and posted them on the Polish Cardiac Society web pages.[3,4] Main recommendations and comments on the problem are presented shortly below.

General recommendations General recommendations concerning all 3 of the abovementioned scenarios are as follows:

- Patients implanted with the S-ICD with the aforementioned risks should be identified and immediately called for check-up during which they should be informed about the situation.
- Remote monitoring is recommended in all patients included in the safety recall, especially those with a history of sustained ventricular arrhythmia and with a limited perception of a beeper. Due to the epidemiologic recommendations related to coronavirus disease 2019 (COVID-19) pandemic, regular telemedical supervision including telemonitoring of the devices seems to have the advantage over the more frequent outpatient visits.[5-7]
- The device should be regularly checked at least once every 3 months, if remote monitoring is impossible.
- During the visit, the device beeper should be demonstrated to the patient signaling the depletion of the battery. The patient's awareness should be raised in terms of reporting all the symptoms suspicious for ventricular arrhythmia (eg, faints, collapse) to the attending physician.

Actions that should be taken when device abnormalities are confirmed were described in detail in expert recommendations.[3,4]

Course of action related to the service action Organizational matters of conducting the service action and implementing the recommendations as well as the level of manufacturer's participation in those actions are subject to the decision of given centers. The Working Group believes—as per previous experiences—that costs of all the actions planned and undertaken by the centers and recommended as part of the safety action, exceeding the guaranteed standard of care for patients with implanted cardioverter defibrillator, should not be paid by the National Health Fund and should be entirely covered by the manufacturer of the device.

Summary The Working Group who prepared the recommendations are fully aware that every surgical procedure in patients with implanted S-ICD is prone to complications. For this reason, the patient's eligibility to the prophylactic S-ICD replacement procedure has to take into account not only the risk of the abovementioned dysfunctions of subset but also additional factors, such as age, comorbidities, and others. The epidemiologic safety related with COVID-19 pandemic should also be taken into account.[5,7]

We support the opinion that in some patients with a low risk of the aforementioned S-ICD subset dysfunctions, the prophylactic device replacement will not be required before reaching

the ERI status as the risk of complications after the device replacement procedure may outweigh the risk of complications related to S-ICD malfunction. Nevertheless, individual clinical circumstances should be considered each time. Actions exceeding the routine standard related to the defined recommendations should be financed by the manufacturer of the device.

ARTICLE INFORMATION

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