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A statement by a Working Group appointed by the National Consultant in cardiology and the Board of the Heart Rhythm Section of the Polish Cardiac Society on the advised conduct in patients with the EMBLEM subcutaneous implantable cardioverter defibrillator by Boston Scientific included in the urgent field safety notice issued in December 2020.

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The Working Group appointed by the National Consultant in cardiology and the Board of the Heart Rhythm Section of the Polish Cardiac Society (hereinafter referred to as the Working Group) presents, as a matter of urgency, crucial information on the threat of the accelerated battery depletion as well as the risk of electrode body fracture in subcutaneous cardioverter defibrillators (S-ICD) by Boston Scientific and submits one's recommendations concerning the conduct in patients with implantable devices, affected by this problem.

An overview of the information released by the manufacturer

The established method of the sudden cardiac death prevention caused by malignant ventricular arrhythmias is the implantation of the subcutaneous cardioverter defibrillator. (1,2) This method has been used in Poland since 2014. (3,4,5)
On the basis of the Boston Scientific Field Safety Notice issued in December 2020, it should be stated that in the implantable S-ICD systems, three independent problems may occur. (6,7) It should be emphasized that more than one of the situations described below may appear in one patient:
1. In some part of the defibrillators models A209 and A219 distributed before August 2018, a premature depletion of the battery may appear due to the malfunction of a low voltage capacitor.
2. In the same models S-ICD produced between May 2015 and December 2017, so called electrical overstress may appear immediately after the delivery of high voltage therapy disabling to download the device data and requiring its replacement, and in extreme cases the possibility of not delivering the high voltage therapy if necessary.
3. Among the patients implanted with the electrode model 3501, the increased frequency of its damage, meaning the electrode body fracture at the location just distal to the proximal sense ring,

was observed. Such a case may cause disturbances in S-ICD sensing, resulting in inappropriate shocks, as well as inability to deliver the efficient high voltage therapy.

In the currently distributed devices, first two problems do not appear, however, the electrode model 3501 is still on the market.

Detailed information (based on materials submitted by the manufacturer) (6,7)

Re 1. The reported problem may apply to approximately 38 350 active devices EMBLEM S-ICD (models A209 and A219). The possibility of its occurrence 5 years after the implantation is estimated currently at 3,7%. The phenomenon in question is caused by the latent release of small amounts of hydrogen within the S-ICD, which may impair the functioning of a low voltage capacitor and may result in an accelerated depletion of the battery. The only subsequent medical consequence of the described malfunction, confirmed so far, is the necessity of the early replacement of the device. The manufacturer's prognosis, based on the examination of the returned devices where the accelerated depletion of the battery occurred, implies that after reaching the ERI status the device should enable at least 21-day therapy.

Boston Scientific declares work aiming to improve the mechanism of battery depletion alert in EMBLEM S-ICD devices in order to detect the described phenomenon earlier. Probably, the implementation of such a mechanism will enhance the patients' safety.

Re 2. Boston Scientific confirmed six (6) events of so called electrical overstress in EMBLEM S-ICD devices that have occurred in association with delivery of high voltage therapy. These events manifested by the inability to interrogate the device or by display of device-based errors/alerts. The presented malfunction may apply to 3350 devices, produced between May 2015 and December 2017. According to the manufacturer, the projected occurrence rate for this electrical overstress behaviour is 0,3% at 5 years. The only known clinical outcome, noted so far, is the necessity of an early device replacement. Although there have been no such cases reported to the manufacturer until present, there is a risk of other serious consequences, including the inability to provide high voltage therapy in case of sustained ventricular arrhythmia.

Re 3. Boston Scientific informs that they have received 27 reports of electrode body fractures of S-ICD system at a location just distal to the proximal sense ring. The problem applies to electrodes model 3501, distributed so far in the number of more than 47 000 items. The cumulative occurrence rate for this case, given by the company, is 0,2% at 41 months from the electrode implantation. The described fracture may result in (depending on the defibrillator settings) records of artifact signals and inappropriate shocks as well as the inability to deliver high voltage therapy in case of ventricular arrhythmia. The detection of the electrode fracture is possible based on non-physiologic mechanical artifacts in S-ICD stored memory observed during the check-up, or induced during the examination, or based on the registered high impedance alert.

In the opinion of the Working Group, the patients at a higher risk of the negative consequences of the premature battery depletion and/or electric overstress and the depletion of the battery resulting thereof and/or the results of possible electrode fracture are the persons:
- with history of sustained ventricular arrhythmia,
- in whom remote or in-office check-up is impossible at least once in 3 months,
- who are unable to hear the beeper.

Recommendations concerning all three of the above mentioned scenarios:

- patients implanted with the S-ICD posing a risk of the aforementioned problems and/or electrode 3501 should be identified in an implantation center. The patients should be immediately called for the check-up during which they should be comprehensively informed about the situation. Presenting the patient with the manufacturer's letter should be taken into account. It is advised to record the visit in medical documentation and to reach the final conclusions, including the decision on the possible replacement of the device

- remote monitoring in all patients included in the safety recall, especially in patients with the history of sustained ventricular arrhythmia and with a limited perception of a beeper, by means of LATITUDE NXT system, if the center has the proper equipment and organizational base. Due to the epidemiologic recommendations related to COVID-19 pandemic, regular telemedical supervision including telemonitoring of the devices in all patients included in the safety recall seems to have the advantage over the more frequent outpatient visits (8,9,10)

- regular check-ups of the device should be run at least once every 3 months, if the remote monitoring is impossible

- during the visit, the device beeper should be demonstrated to the patient using the Test Beeper function signaling the depletion of the battery.
The patient should be instructed on the immediate reporting to the implantation center in case of hearing the beeping tone. The demonstration of the beeper should be repeated after each examination following MRI scan, as strong magnetic fields may cause permanent loss of beeper volume. The patient's awareness should be raised in terms of reporting all the symptoms suspicious for ventricular arrhythmia (e.g. faints, collapse) to the attending physician.

Moreover:

a) in a situation described in point 1 (premature battery depletion caused by the malfunction of a low voltage capacitor):

- the symptoms of the premature battery depletion should be immediately reported to the manufacturer in order to determine the exact date of the procedure of device guarantee replacement

- every EMBLEM S-ICD device with a confirmed accelerated battery depletion should be subject to guarantee replacement within 21 days from ERI indication. Moreover, in high risk cases, taking into account the patient's preferences, prophylactic guarantee replacement should be considered in other cases

b) in a situation described in point 2 (electric overstress following high voltage therapy):

- S-ICD check (in-office or remote by means of LATITUDE NXT system) should take place immediately after every high voltage discharge

- inability to obtain the data from the device during check-up, the symptoms of the premature battery depletion or the emergence of the prolonged charging time alerts should be promptly reported to the manufacturer in order to determine the necessity of a possible guarantee replacement of the device

- every EMBLEM S-ICD device, in case of an electric overstress should be instantly replaced under the guarantee. Moreover, in high risk cases, also taking the patient's preferences into account, prophylactic guarantee replacement of the device should be considered in other patients

c) in a situation described in point 3 (electrode fracture):

- during every check-up, all the reasons of the high impedance alerts should be examined as they may imply electrode body fracture. Electrocardiographic records of the stored events should be analysed in search for artifacts. All the sensing vectors should be recorded and analysed in respect of the following occurrences, in every of which it may signify the onset of the electrode body fracture:

- cardiac signals in the Primary and Secondary vectors looking almost identical;
- flatline record in the Alternate sensing vector.

Sensing performance during isometrics and/or posture changes should be assessed. If isometrics and/or posture changes provoke non-physiologic artifacts, this may indicate the onset of the electrode body fracture. In such a case, it is necessary to use X-ray imaging in an attempt to visualize the fracture.

- every electrode with a confirmed fracture, after the consultation with the manufacturer, should be subject to an immediate guarantee replacement. Prophylactic replacement of a functioning electrode is not recommended. Considering the infection risk as well as the other complications of S-ICD replacement, during the electrode replacement, once the level of S-ICD battery depletion is significant, the device should be simultaneously replaced as part of the safety recall.

The 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 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 the costs payed by the National Health Fund and should be entirely covered by the manufacturer of the device.

Summary

The Working Group preparing the recommendations is 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 must take into account not only the risk of the above mentioned dysfunctions of subset, but also additional factors, such as: age, co-morbidities and the patient's applied treatment (including mainly anticoagulant treatment), estimated time to the prospective device replacement, the patient's ability to hear the beeping tone as well as the patient's or the patient's family reaction to its' occurrence, the possibility of a phone contact with a patient or their family and the patient's overall psycho-physical fitness. In the nearest, unspecified period of time, in the patients' global safety evaluation, the epidemiologic safety related to COVID-19 pandemic should also be taken into account. (8)

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 along with all the aforementioned factors. Actions exceeding the routine standard related to the defined by the Working Group recommendations should be financed by the

manufacturer of the device by means of individual agreements with the centers participating in the action.

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