Canadian Heart Rhythm Society
Société canadienne de rythmologie

July 5th, 2017

Canadian Heart Rhythm Society
Device Committee

RE: Boston Scientific SICD VF induction advisory

Nature of the Advisory:

Boston Scientific has released an advisory regarding an event that occurred with an Emblem SICD. A malfunction in the device caused the SICD to spontaneously induce ventricular fibrillation in a patient which resulted in the patient's death. A subsequent analysis showed that memory corruption at two locations caused the device to activate the VF induction stimulation which continued until the battery was depleted. It was felt that this memory corruption was caused by unavoidable background radiation.

Scope of the problem:

The malfunction was caused by two separate memory corruptions which both had to happen to cause the device to deliver VF induction energy. A repeat failure of this type is felt to be possible but very unlikely in all present first and second generation SICD devices, both implanted as well as those on the shelves. The estimated risk of this failure happening again has been calculated to be 1:300,000 over 5 years for patients with these devices.

Boston Scientific is working on a software patch which will prevent the devices from delivering this kind of induction energy except during an active telemetry session. This patch will prevent the devices from delivering any induction or pacing energy in case of any further malfunctions, and will prevent any possible harm from similar memory failures once applied. This patch is expected by the end of the month and will be forwarded to Health Canada for approval before being uploaded to all SICD devices. Until that patch is available, all devices are subject to this small risk of malfunction.

Response of the CHRS Device Committee:

While the risk of this event recurring is small, the consequences are severe. Therefore, we are making the following recommendations:

1 All patients with SICDs in place should be notified of this advisory. They should be reassured that the risk of this happening again is exceedingly low, and that a software fix is coming.
2 Patients with SICDs should continue routine clinical follow-up. More intensive follow-up would not alter the risk or outcomes of this issue.
3 Boston Scientific recommends avoidance of excessive radiation exposure for these devices. However, they admit that the affected device had no known exposure above normal background levels and it is uncertain if this would affect risk.
4 We have recommended suspension of trials that could randomize patients to receive SICD therapy when other options are available. This includes MADIT SICD in the US (which was already suspending enrollments due to this issue), and ATLAS in Canada. Dr. Jeff Healey (PI for ATLAS) has agreed to suspend randomization in this trial until the software fix becomes available.
5 Centers should consider whether to hold off on SICD implants where transvenous devices can be used. Many on the core committee feel no SICDs should be implanted with this vulnerability if a transvenous option is available, however in certain circumstances where an SICD would have significant clinical advantages they may still be considered. If a patient does have an SICD implant prior to the software patch becoming available, full disclosure of this issue must be explained to the patient prior to implant.

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