Canadian Heart Rhythm Society
Société canadienne de rythmologie

January 20, 2019

Canadian Heart Rhythm Society
Device Committee

RE: ADVISORY: Medtronic pacemakers – risk of circuit error with loss of ventricular pacing output for a subgroup of Adapta, Versa, Sensia, Relia, Attesta and Sphera pacemakers.

Nature of the Advisory:

The advisory covers a subset of Medtronic pacemakers distributed world wide from March 2017 to January 2019. The problem is a 'circuit error' which happens when the device is in an atrial tracking mode. This error occurs only when a specific combination of events occur while the device is processing an atrial sense event, and the pacemaker then cannot deliver a ventricular pacing output until there is a ventricular sensed event. In the case of a pacemaker dependent patient or a patient with long periods of AV block there may be prolonged loss of ventricular output which could result in patient syncope or rarely death.

Medtronic is working on a software update that will correct this issue, but the availability of that update will not be until the latter half of 2019.

Scope of the problem:

The risk of this circuit error only occurs in specific pacemakers manufactured with a specific integrated circuit. Worldwide these circuits have been used since March 2017 but have only been approved in Canada since July 2018. The error has been seen in 3 devices worldwide out of 150,000 devices at risk. In Canada there have been 792 at risk pacemakers distributed, with 419 devices implanted and the rest listed as 'on consignment' and not yet implanted. Those at-risk devices have been removed from hospital inventories.

Medtronic estimates the risk of a pause due to this error being 2.8% per month which varies depending on patient factors. The highest risk would occur in patients who are pacemaker

dependent or potentially in those in whom the presenting rhythm was syncope with AV block and a limited escape rhythm.

Recommendations of the CHRS Device Committee:

We recommend that all patients with affected devices be notified of this advisory. Regardless of the management for any specific patient, all patients should be notified to contact their pacemaker clinic immediately if they develop symptoms of presyncope, syncope, or other possible symptoms of prolonged pauses.

The risk to patients with this error depends on specific programmed settings and patient factors. As such, the recommendations need to be tailored to the specific patient.

1 For patients in whom atrial tracking is **not** necessary, reprogramming to a ventricular only pacing mode (VVI or VVIR) will eliminate the risk. If the patient is already in that mode no further changes are necessary.

2 In patients who clinically need atrial pacing but have no intrinsic AV conduction abnormalities, programming to AAI/R or MVP mode will provide atrial pacing with intrinsic AV conduction providing ongoing ventricular activity. These patients would be at low risk of long pauses, thus programming to these modes would provide adequate patient safety.

3 In patients who require ventricular pacing and atrial tracking (those who cannot tolerate prolonged VVI or VVIR pacing), this error could lead to significant pauses in cardiac output which could lead to adverse clinical outcomes. In these patients, device replacement should be considered due to the ongoing risk until the software update is available. This consideration especially applies to those patients with AV block and no escape rhythm and those patients with a pacing indication of syncope due to AV block.

If the decision for patient care is to program the system to a non-tracking mode to avoid the vulnerability, it is important to notify the patient and any other clinics that may look after the patient that they should not be reprogrammed into a potentially susceptible mode until the software fix is applied.

Thank you,

Larry Sterns, Chair,
On behalf of the CHRS device committee,
Drs. Francois Philippon, Ratika Parkash, Derek Exner, and Raymond Yee