Australian Government
Department of Health
Therapeutic Goods Administration

Programmable VT detection in cardiac resynchronisation therapy defibrillator (CRT-D) devices

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Clinicians need to tailor the device programming of CRT-D devices to each patient to ensure the delivery of therapy when needed, while at the same time avoiding inappropriate shocks for non-life threatening rhythms.

CRT-D devices deliver cardiac resynchronisation therapy and include an implantable cardioverter defibrillator. They are used for diagnostic and treatment modalities including cardiac resynchronization therapy, bradycardia pacing, and ventricular tachyarrhythmia therapy (such as ventricular tachycardia - VT).

VT is a type of broad complex tachycardia originating in the ventricles of the heart. Other than clinical features, VT may be distinguished through its morphology and duration on ECG. CRT-D devices may include detection-enhancement programmes that aim to differentiate between physiologic sinus tachycardia, which typically begins slowly, from pathologic tachycardias such as VT, which typically begin abruptly. They may measure the rate of transition in the ventricular rhythm from slower rates to tachycardia, and if the rate increase is gradual, such devices may enable inhibition of ventricular therapy.

These devices utilise programmed thresholds and algorithms to make decisions. Thus, they do not know whether a particular rhythm is for example truly VT; they can only make decisions based on quantifiable parameters such as whether given intervals are faster (or slower) than the programmed threshold, or whether the rhythm should be classified as sudden/gradual, stable/unstable, and correlated/uncorrelated.

These programmes may operate differently across devices from different manufacturers. In general, programming such devices requires a balance between ensuring that life-saving therapy will be delivered, and avoiding therapy for non-life-threatening rhythms (e.g. supraventricular arrhythmias), which could paradoxically compromise patient safety. Examples of possible programming features to be aware of include, but are not limited to: interval-based discriminators that detect the onset of sinus tachycardia compared with VT, the delay or withholding of therapy if acceleration across the sinus-VT rate boundary is gradual, the ability to override therapy inhibition, and the ability to bypass a sequence of ATP therapy in favour of shock therapy.

TGA review of incident

The TGA received an adverse event report for a patient implanted with a cardiac resynchronization therapy defibrillator. The patient went into VT and received four bursts of anti-tachycardia pacing (ATP), successfully converting the arrhythmia. Seconds later, the patient went back into VT. The device inhibited therapy based on the rhythm onset being classified by the device as gradual.

Approximately three and a half minutes later the rhythm accelerated into the ventricular fibrillation (VF) zone and one burst of ATP was delivered. The rhythm did not convert and a 41 Joule shock was delivered by the device, converting the arrhythmia. However, the patient then went into a slow VT, for which no therapy was programmed to be delivered. Within one hour of these episodes, the patient required resuscitation in the Emergency Department and could not be revived.

Detailed review after this incident concluded that the device did not malfunction and operated as it was programmed.

There have been no other similar events for this device in Australia for the last three years.

Individual programming required

For all devices of this nature, please note that the device may withhold the delivery of ATP or shock, such as for cases of VT that are categorised as gradual onset, do not exceed the rate criteria, or do not meet other programmed thresholds. These devices need to be programmed by clinicians for each patient. It is therefore paramount that clinicians continue to evaluate and monitor the programmable device settings of each patient implanted with these devices.

The clinician needs to balance the device programming to ensure the delivery of therapy when needed, while at the same time avoiding inappropriate shocks for non-life threatening rhythms. The information for users provided for each device should enable clinicians to determine when a particular programming setting or a combination of settings is appropriate (or not) for each specific patient.

What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues

- labelling, packaging or manufacturing deficiencies
- software deficiencies
- device interactions
- user/systemic errors.

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at Report a problem (//www.tga.gov.au/reporting-problems)
- **by emailing** iris@tga.gov.au (mailto:iris@tga.gov.au)
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713.

For more information about reporting, visit www.tga.gov.au (http://www.tga.gov.au) or contact the TGA's Medical Devices Branch on 1800 809 361.

Disclaimer

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