A Novel Algorithm Improves Detection of Arrhythmias with Regular RR Intervals in Implantable Cardiac Monitors

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BACKGROUND

Implantable cardiac monitors (ICM) are used to automatically detect arrhythmias such as atrial fibrillation (AF), and regular atrial tachycardias/flutter (AT). Existing ICM algorithms require the same duration parameter for AF and AT.

- When detection of short AF episodes is desired (i.e. cryptogenic stroke), short episodes of regular RR rhythms may also be reported.
- The resultant high number of false positives (low PPV) due to frequently confounding regular RR rhythms such as sinus tachycardia requires that AT algorithms be turned OFF.
- Likewise, regular AT/flutter rhythms often go undetected with these existing algorithms

The objective of this work was to evaluate the *in silico* performance of a novel algorithm that allows detection duration for AF and AT to be programmed separately.

METHODS

AF and AT algorithms were developed and tested on wideband, high resolution, 12-lead Holter ECG data from 6 different clinical studies (2010 total pts – 223.6 days, 77 AF pts – 5.2 days; 6 AT pts – 3.7 days) (Telemetric and Holter ECG Warehouse, U. Rochester)

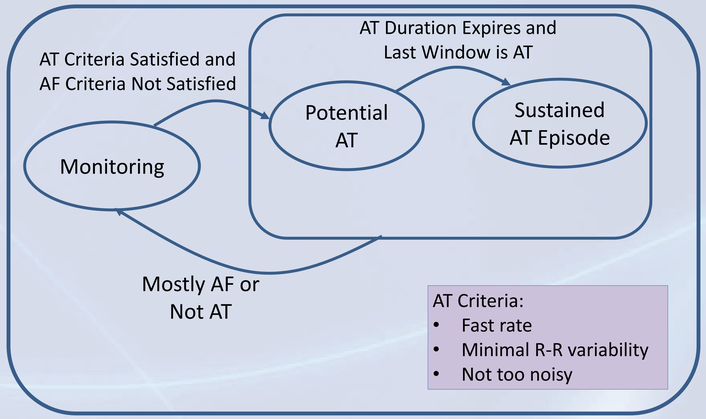
The V2-V3 vector was used to simulate the implanted ICM signal and was evaluated using a MATLAB model of ICM sensing hardware, as in prior analyses presented at this meeting[1,2].

The AF algorithm was run at 2-minute duration while the short duration AT algorithm (SDAT) was programmed to 15 different rate and duration settings.

METHODS (SDAT Description)

- When SDAT is ON, it waits in the Monitoring state until detecting a 2-minute period satisfying the AT criteria but not AF.
- When an AT window is detected, then SDAT moves to the Potential AT state.
- SDAT transitions from the Potential AT state to Sustained AT when the programmed SDAT duration expires and the last window is AT.
- SDAT transitions from either Potential AT or Sustained AT to Monitoring when more than 50% of the windows are classified as AF or a single window does not meet the AT criteria

SDAT State Chart



RESULTS

PPV for combined AF and AT detection increased from 54% to 97% with both higher rates and longer durations (Fig 1A).

AT Sensitivity ranged from 52% to 87% and decreased with increased detection duration (Fig 1B).

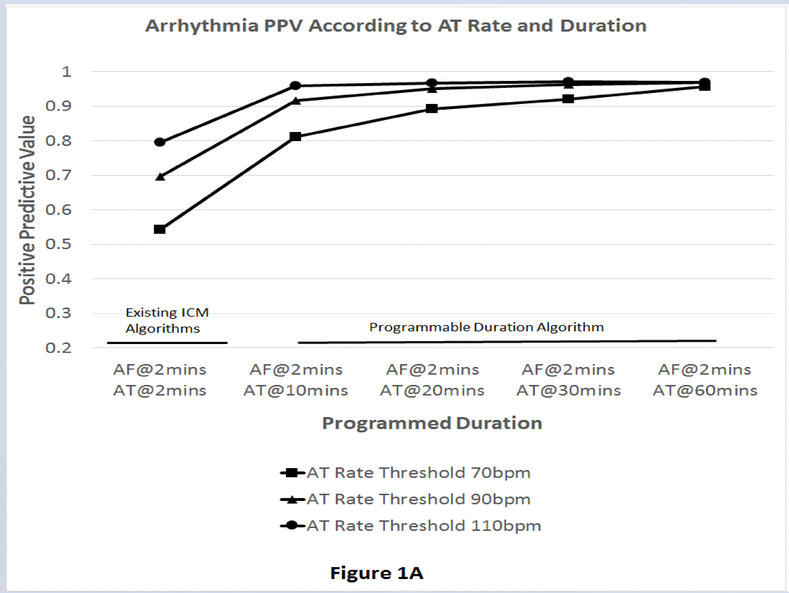


Figure 1A

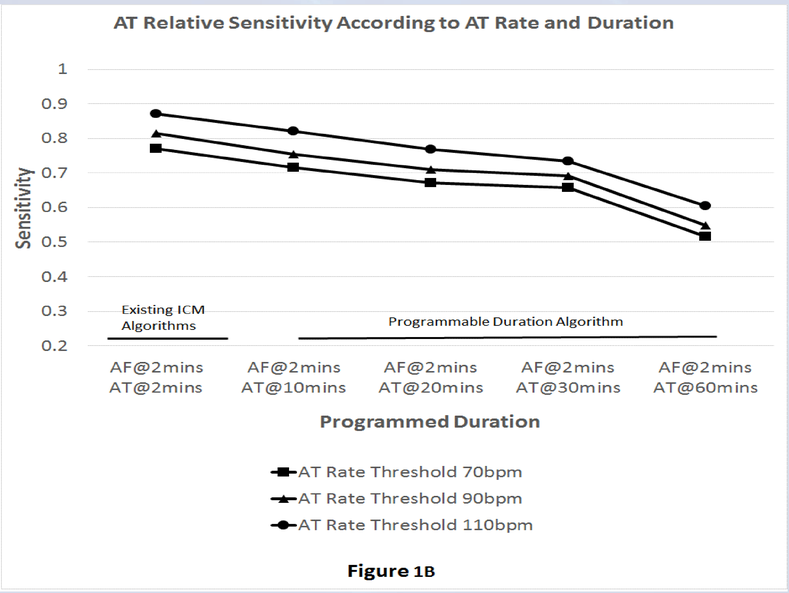


Figure 1B

CONCLUSIONS

A high PPV for both AF and AT can be achieved while maintaining AF detection sensitivity for short durations. This has important implications for minimizing clinic workload in those patients in whom detection of short AF durations is desirable

LUX-Dx™ Insertable Cardiac Monitor System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "User's Manual" for more information on Indications, Contraindications, Warnings, Adverse Events, and Operator's Instructions.

INDICATIONS
The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous ECG (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath.
The LUX-Dx has not been tested specifically for pediatric use.

CONTRAINDICATIONS
There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically-inserted device.
LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device.

WARNINGS
Concomitant use of the ICM system and implanted electro-mechanical devices [for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-implanted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the ICM system when used in combination with the co-implanted device.
Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury.
The influence of medical equipment on implanted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards.
Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device.
The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other implanted devices. It can also permanently disable some magnetic strip cards. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app.
The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices.
Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result.
Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.
Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients.

PRECAUTIONS
For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal.

POTENTIAL ADVERSE EVENTS

Potential adverse events related to insertion of the device may include, but are not limited to, the following:

- Device migration
- Erosion
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Infection
- Local tissue reaction
- Tissue damage

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required.

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