Improved AF Rhythm Discrimination with an Implantable Cardiac Monitor Using QRS Morphology

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Disclosures: **S. Mittal:** Consultant - Boston Scientific Corp.; **S. Saha:** Equity Interests/Stock Options – Boston Scientific Corp.; Salary - Boston Scientific Corp;
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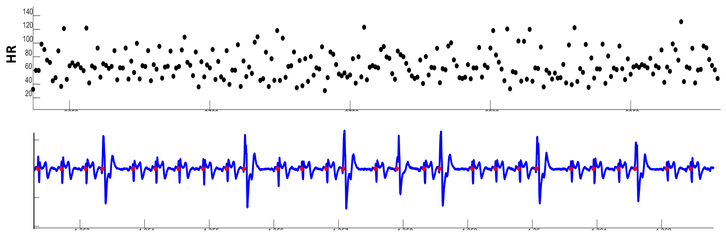
Background

Implantable cardiac monitors (ICM) are commonly used to automatically detect atrial fibrillation (AF). Many existing AF detection algorithms are initially triggered by R-R interval variability and are associated with high false positive rates. Real-world evaluations of AF algorithms in ICMs have reported positive predictive values (PPV) ranging from 26% to 84% for episodes ≥2 minutes.[1]

Morphology assessment helps identify non-sinus beat detections such as:

- PVCs
- T-waves and P-waves
- Noise and motion artifacts

The objective of this work is to assess the potential gains in AF episode detection performance via use of QRS morphology.



Example of an AF false positive episode detected when only using R-R variability

AF Trigger → **Morphology Assessment** → **Morphology Classification**

Identifies potential AF windows based on R-R interval variability over a 2 minute window

Compares each beat to a template; computes a Morphology Score

Evaluates morphology scores in the window. Makes a determination of AF or Non-AF based on number of morphology matched beats

[1] Mittal et al. Real-world Performance of an Enhanced Atrial Fibrillation Detection Algorithm in an Insertable Cardiac Monitor. Heart Rhythm Society, 2016: 13 (8): 1624-1630.

Data used for this research was provided by Telemetric and Holter ECG Warehouse (THEW), University of Rochester, NY.

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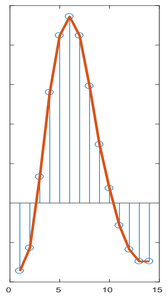
Methods

The performance of the AF algorithm with and without morphology assessment was determined at 5 AF sensitivity settings over a 2 minute window. The threshold of morphology matched beats required to declare AF changes with each sensitivity setting.

12-lead ECG data (Telemetric and Holter ECG Warehouse, U.Rochester) were used to assess the AF algorithm. The ECG vector V2-V3 was derived and used to approximate the ICM configuration.

Signal morphology of each beat in a 2-min window was compared to a QRS template.



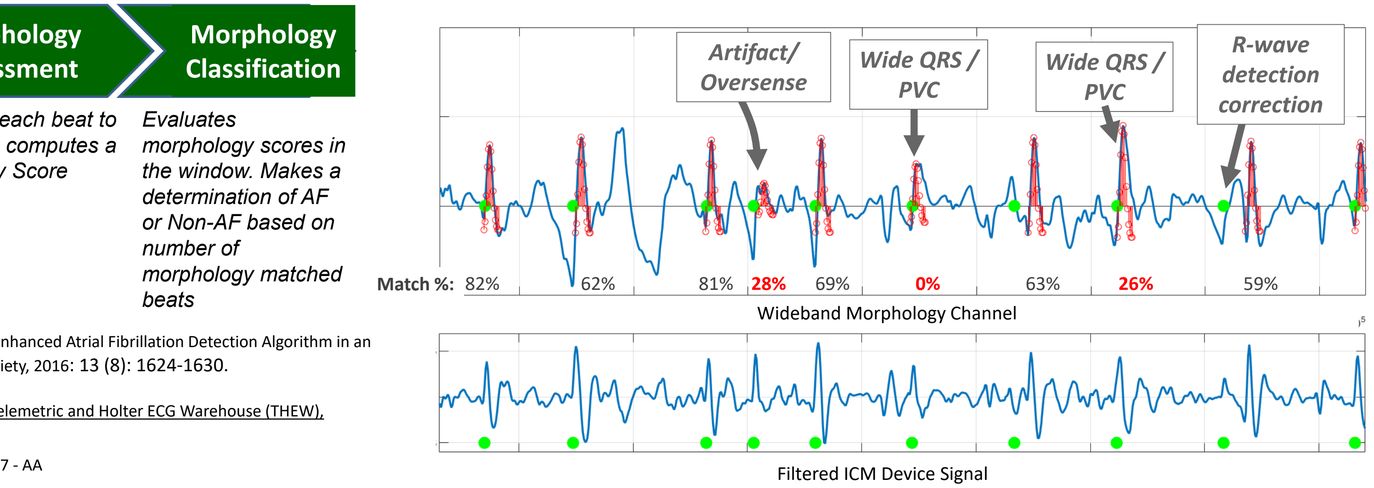
Sample morphology template. Points are chosen to adequately represent the dominant peak of the QRS complex

There are 2 morphology templates built that encompass the QRS complex:

1) based on stable normal sinus beats (static) for ectopy and noise rejection, or
2) based on the previous beat (dynamic) to accommodate AF with aberrancy

The template can be updated over time based on various triggers. It is compared to each detected beat in the AF window and a match score for that beat is calculated based on the degree of match.

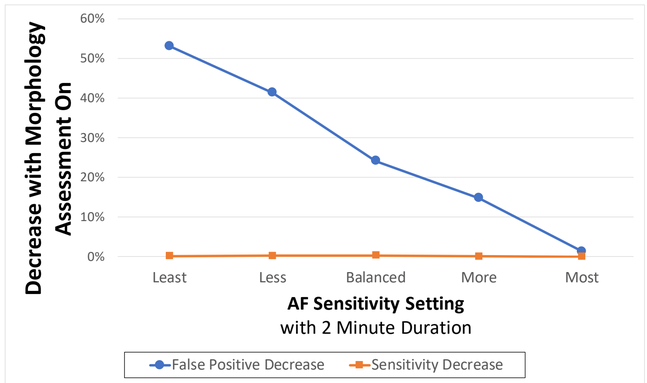
- The percentage of mismatched beats in each window was compared to a threshold specific to the AF sensitivity setting, and used to reject false AF.

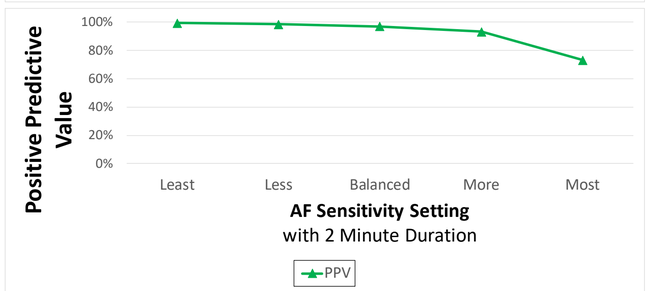


Results

Patients	2040
AF Patients	77 (3.8%)
AF Patients with aberrancy	9
Total EGM duration	5377 hrs
AF duration	129 hrs (2.4%)

A total of 161,306 2-min windows (3872 AF) were assessed. Using morphology, results ranged from 1.3% - 53.1% relative reduction in false positives, with a corresponding 0% - 0.18% decrease in relative sensitivity between the 5 sensitivity settings. The AF Burden PPV using morphology ranged from 73.3% to 99.4%.





Conclusions

Incorporating QRS morphology assessment in addition to R-R variability can meaningfully reduce false positives in AF detection with minimal impact to sensitivity. Despite a low AF prevalence, a high positive predictive value was achieved.

LUX-Dx™ Insertable Cardiac Monitor System

INDICATIONS

The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (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.
92496928 (Rev. B)

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.*