A Novel Algorithm Reduces False Positives for Pause Detection in Implantable Cardiac Monitors

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BACKGROUND

Implantable cardiac monitors (ICM) are used to identify significant pauses in patients with unexplained syncope. Existing ICM algorithms suffer from a large number of false positive results which increases clinic workload.

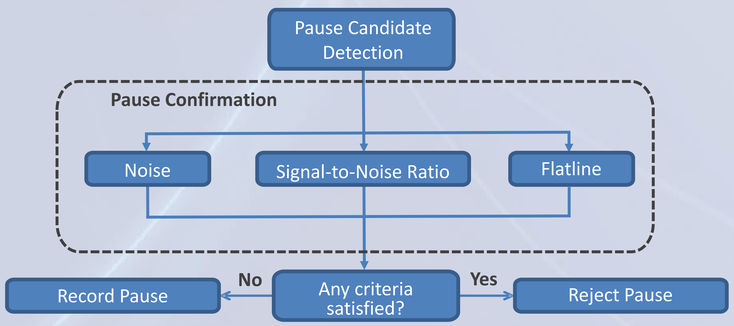
Objective: To evaluate the performance of a novel pause detection algorithm, which maintains high sensitivity while reducing false positives.

METHODS

We created a Matlab model for ICM sensing and pause detection utilizing filtering, R wave detection, and noise rejection techniques from Boston Scientific ICDs. The pause algorithm uses a proprietary two-step trigger and confirm process:

- detect a suspected pause when an R-R interval is longer than a programmed threshold
- confirm (or reject) a suspected pause after analyzing for broadband myopotential noise, signal-to-noise ratios (undersensing), and non-physiologic flat signals (loss of electrode contact).

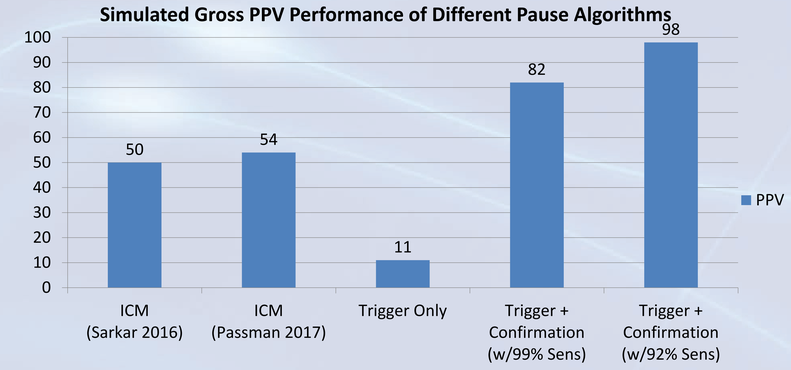
V2-V3 vector data from Holter monitor recordings (n=673) were evaluated for 3-second pauses in 4 different settings: less, nominal, higher, and most sensitive. 1454 suspected 3-second pauses were adjudicated as either true-pause (166) or false-pause (1288).



Passman RS et al. 2017 *Heart Rhythm* v14:1016-1023
Sarkar S et al. 2016 *Heart Rhythm* Supplement v13:S16 AB07-05

RESULTS

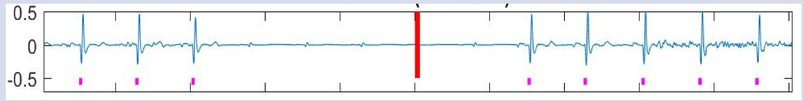
Sensitivity performance for 3-second pauses from the 4 settings ranged from 92% - 99% and Positive Predictive Value (PPV) ranged 82% - 98%. PPV for suspected pauses (no confirmation step) was 11% for 3-second pauses.



DISCUSSION

Two stage algorithm: Trigger and Confirm

Trigger stage identifies potential pauses with long R-R interval

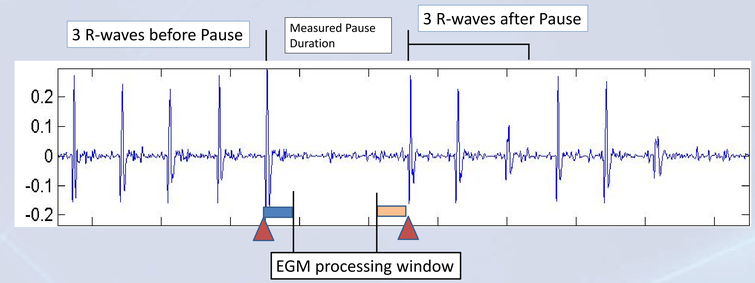


Trigger stage alone yields excessive false positives, caused by:

- Myopotential noise that raises the sensing threshold
- Undersensing due to posture changes and low amplitude PVCs
- Large amplitude ectopic beats and noise spikes
- Missing signal (flatline), due to amplifier saturation or loss of electrode contact

Confirm stage revisits potential pauses using three methods

- Detect broadband myopotential noise (via Dynamic Noise Algorithm filter)
- Measure Signal-to-Noise ratios to determine likelihood of R-wave under-sensing
- Identify flatline (loss of signal) conditions



CONCLUSIONS

This new pause detection algorithm maintained high sensitivity and PPV, and performed favorably compared to existing algorithms.

- The algorithm performs well in several challenging clinical contexts as outlined in the examples above.
- Improved pause detection performance could markedly improve accuracy and efficiency in the device clinic.
- Work to evaluate the in vivo performance of this algorithm is currently underway.

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

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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