Improved Detection of AT *In Vivo* in Patients with the LUX-Dx Insertable Cardiac Monitor

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BACKGROUND

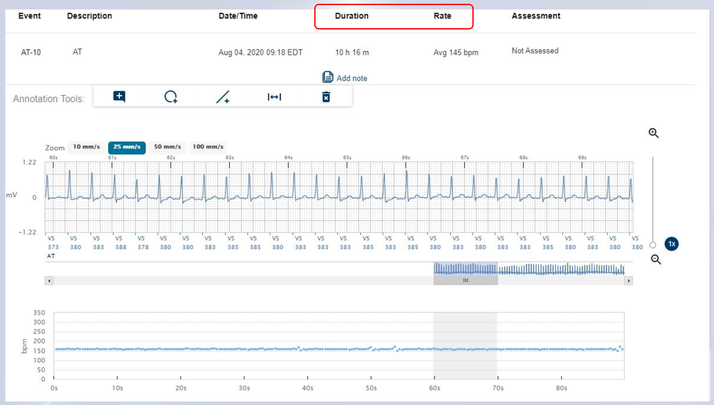
Insertable cardiac monitors (ICMs) detect atrial fibrillation (AF) and atrial tachycardias/flutter (AT) in a variety of clinical contexts: syncope; cryptogenic stroke; and rhythm management.

Currently available ICM algorithms require the same episode duration setting for AF and AT. A short duration setting for AF causes false positive AT episodes due to confounding regular R-R rhythms (e.g. sinus tachycardia). However, turning AT features off prevents detection of clinically relevant AT such as typical/atypical atrial flutters.

Previous work [1] has shown improved *in silico* detection of AT with regular R-R intervals by decoupling AT and AF durations. Here, we describe performance of that algorithm *in vivo*. Data from both a small cohort (single site) and larger database (LATITUDE™; multi-site) were analyzed.

SINGLE SITE

We reviewed data from patients implanted with the LUX-Dx ICM at a single center (n=40; avg 49 days/patient). All detected AT episodes were adjudicated; sample shown below. Algorithm performance is characterized in Table 1.



The AT algorithm (nominal setting: >110bpm/4 hours) was programmed to 4 hours for 24 patients and 2 hours for 16 patients; all were programmed to >110 bpm.

AF episodes (534) were detected in 10 patients; AT episodes (47) were detected in 10 patients; 6 patients with AT episodes did not have detected AF episodes. Four of these were adjudicated as atrial flutter; the other two were persistent sinus tachycardia.

Table-1	All Patients Pts (Episodes)	Cryptogenic Stroke Pts (Episodes)	Syncope Pts (Episodes)	Rhythm Mgmt Pts (Episodes)
Patients	40	14	4	19
AF Total	10 (534)	3 (90)	0 (0)	7 (444)
AT Total	10 (47)	3 (17)	1 (1)	6 (29)
AT and No AF	6 (26)	2 (13)	1 (1)	3 (12)
% AT Only Detection	15%	14%	25%	16.0%

MULTI-SITE

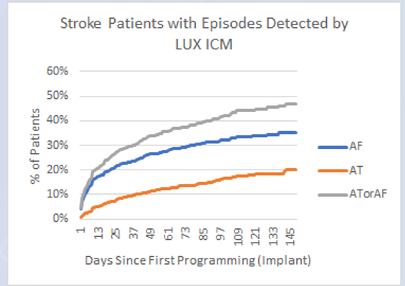
Deidentified data from LATITUDE Clarity were analyzed and characterized by the presence of AF and/or AT detection. A total of 3736 patients and 1705 episodes were analyzed; these episodes were *not* adjudicated. Data both total and broken down by indication is shown below. Across the board, a significant number of patients with AT alone were identified; mean time to detection 28 days. Furthermore, in 30 of 285 patients who had both AF and AT, the AT was detected a mean 26 days prior to AF.

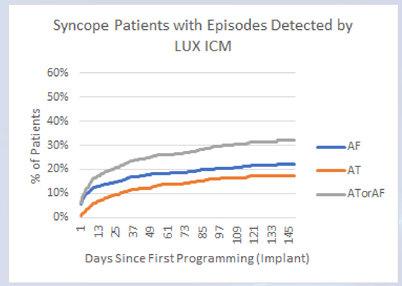
Total Pts	3736			
		AT	No AT	Total
	AF	285	889	1174
	No AF	246	2316	2562
	Total	531	3205	

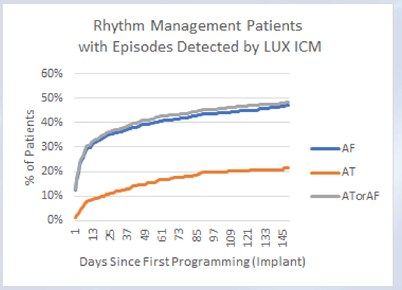
Stroke Pts	1202			
		AT	No AT	Total
	AF	54	267	321
	No AF	93	788	881
	Total	147	1055	

Rhythm Mgmt Pts	1233			
		AT	No AT	Total
	AF	178	427	605
	No AF	31	597	628
	Total	209	1024	

Syncope Pts	1301			
		AT	No AT	Total
	AF	53	195	248
	No AF	122	931	1053
	Total	175	1126	







When broken down by rhythm (AT, AF, or both) and indication, interesting trends are identified. In both syncope and stroke patients, AT alone contributes significantly to overall rhythm burden with time. In the rhythm management group, AT and AF appear to track together far more frequently; this could clearly reflect selection bias as many of these patients have already been diagnosed and/or had ablations.

CONCLUSIONS

The ability to program separately AF and AT durations enables detection of clinically relevant AT without compromising ideal AF detection settings. In a significant number of patients (n=276, 7.4%), the early detection of AT would allow for earlier implementation of oral anticoagulant therapy; this might translate into improved outcomes. Mean time to AT detection in the absence of AF was 28 days and in the presence of AF, 26 days prior to AF. Not surprisingly, patients in the rhythm management arm, many of whom already carried an AF diagnosis, appeared to have concomitant AF and AT.

[1] Richards et al., 2019. A novel algorithm improves detection of arrhythmias with regular RR intervals in implantable cardiac monitors. *Heart Rhythm* 16(5) May Supplement.

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 use, please see the complete "User's Manual" for more information on Indications, Contraindications, Warnings, Adverse Events, and Operator's Instructions.