

Feasibility Study of an Implantable Device to Monitor ST-Segment Shifts and Alert Patients to Cardiac Ischemia

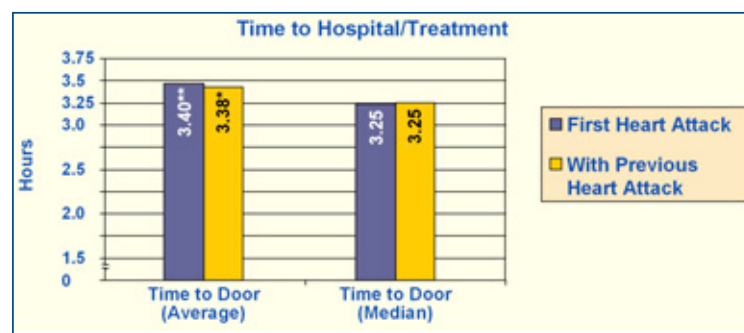
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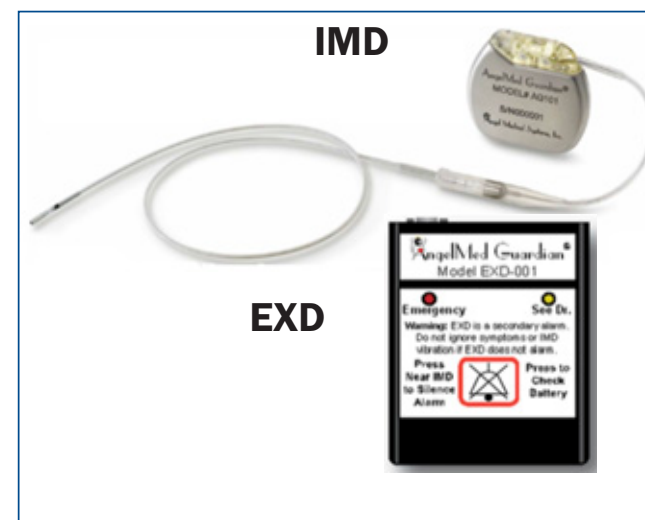
Background

AMI remains a leading cause of death in the United States and the Western World [1]. Early detection and patient alerting of coronary occlusion or plaque rupture which occurs before or coincident with symptom onset could allow prompt evaluation and treatment to improve clinical outcomes [2]. Historical efforts to reduce the delay between AMI symptom onset and arrival at a medical facility have failed to significantly reduce the typical 3 hour delay [3]. This delay does not change for patients on second or later heart attacks as seen in the data from the TIMI group in the figure below.



The DETECT study completed in mid 2009 evaluated whether intracardiac electrogram ST-shift monitoring could be used as a safe and reliable indicator of cardiac ischemia. The study was also designed to determine if ST-shift detection thresholds calculated from daily-life monitored data (i.e. a self-norm) could be used to set ischemia detection thresholds in a reliable manner.

DETECT is the first United States investigation of an implanted real-time ECG monitoring system for ischemia detection and patient alerting. The implantable AngelMed Guardian® system (Angel Medical Systems, Inc., Shrewsbury, NJ) includes an implantable device (IMD) connected to a standard pacemaker right ventricular lead and provides an internal vibratory alert. An external pager-device (EXD) also alerts the patient with auditory and visual warnings when medically relevant ischemia detection occurs. The IMD and EXD can communicate at distances of up to 6 feet.

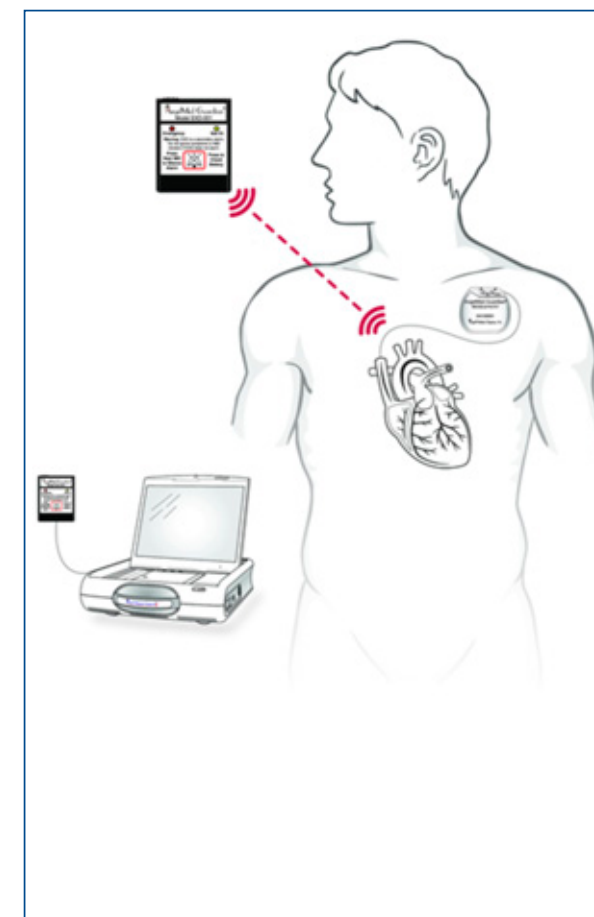


Methods

Patients: Seventeen patients with high-risk acute coronary syndromes underwent implantation at three clinical sites with the Guardian that provides continuous evaluation of "ST shifts".

Ischemia detection: The ST-shift measure is derived by subtracting the prior PQ-segment of a beat from the ST-segment and comparing this difference to the average ST-PQ value for a preceding 24 hour baseline period (patient self-norm). ST-Shift% is ST-Shift, normalized to the average R-wave height of the baseline. Ischemia detection thresholds are generated shortly after the device is implanted using an algorithm called AUTOPICK. This uses the prior 14-days of ST-shift data and sets detection thresholds based upon the mean and standard deviation of this sample. Different ischemia detection thresholds are set for several discrete heart rate ranges. For the device to alert the patient, the ST-Shift% values of the analyzed heartbeats must be classified as ischemic for at least 70 seconds.

Patient alerting: DETECT patients were trained to respond to two different types of alarms: an "Emergency Alarm" and a lower level "See Doctor" Alert. The Emergency Alarm causes the implanted device to vibrate and the pager device to emit sonic "beeps" in a 3-2-3-2 pattern corresponding to the international standard for high priority medical alarms. Patients are trained to call 911 for any Emergency Alarm as it may be indicative of detection of a heart attack.



Results

Throughout 12 months of follow-up, five of 17 patients had ST-shifts that were sufficient to trigger emergency alarms and seek medical attention. Two were documented with angiographic/intravascular ultrasound thrombotic occlusion events, two had heart-rate related ischemic events associated with significant coronary stenosis. One subject had a 1st false positive (FP) alarm from an arrhythmia that required device reprogramming for R-wave measurement and a 2nd FP alarm due to a re-programming error that was immediately corrected. No false negative events occurred during the study period. With the exception of measurements prior to Emergency Alarms, the ST-Shift% measurements for the study population remained stable and typically displayed distributions of $\pm 10\%$ of baseline R-wave height (see Fig 2). Detected ischemic events were typically 2 to 4 times the largest value of the non-ischemic ST shift (See Fig 3). There were no clinically significant adverse events.

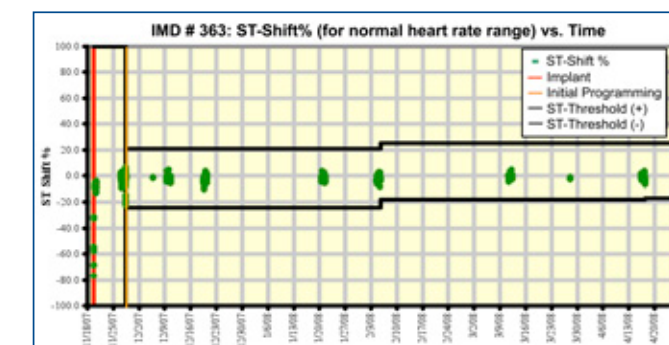


Fig 2: Sample ST-shift data (green dots) for heartbeats in the normal heart rate range (42-85 BPM) of a DETECT patient with no complications during 5 months of monitoring. The black lines were set for positive and negative ischemia detection thresholds guided by AUTOPICK.

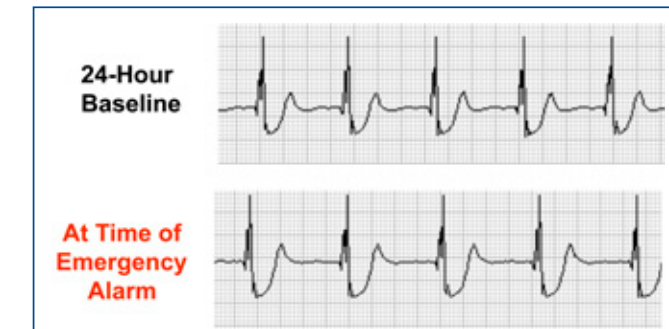


Fig 4: Electrogram traces from the second event of Fig 3, showing the patient's baseline from 24 hours before and the data that triggered the emergency alarm.

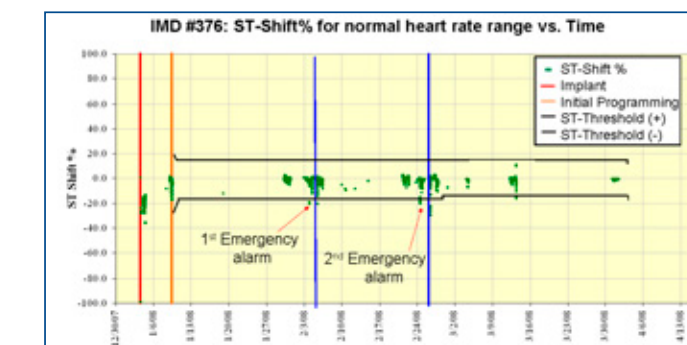


Fig 3: ST-shift data for a patient who had two confirmed coronary events, with IVUS confirmation of the ruptured plaque site (LAD) for the second event. In each case the patient rapidly responded to the Emergency Alarm and upon medical evaluation, a culprit lesion was found. Blue bars indicate stenting with associated ST-shift changes.

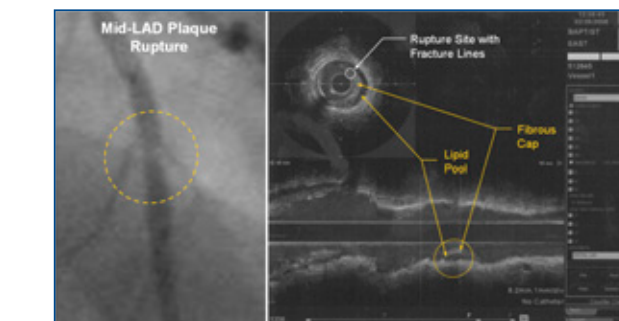


Fig 5: Angiogram and IVUS confirmation of the ruptured plaque site that triggered second event for the patient of Figs. 3 and 5. For each event the patient properly responded to the Emergency Alarm and a culprit lesion was found in his LAD.

Conclusions

The DETECT study has demonstrated the ability of the Guardian implantable intracardiac ischemia detection system to identify clinically significant ST shifts caused by coronary ischemia or stenosis. ST Shift compared to a 24-hour baseline is promising as a stable measure which deviates in response to coronary occlusive events. Detection thresholds using the AUTOPICK automated software based on each patient's self-norm distribution of ST deviation over a 14 day period produced clinically relevant threshold levels for ischemia detection. The Guardian is now undergoing a 1,000 patient multi-center randomized study to assess clinical benefit.

References

1. *Heart and Stroke statistical Update*. Dallas, Tex: American Heart Association; 1999.
2. Canto JG, Zalenski RJ, Ornato JP, et al. Use of emergency medical services in acute myocardial infarction and subsequent quality of care observations from the national registry of myocardial infarction 2. *Circulation* 2002;106:3018-3023.
3. Ryan TJ, Anderson JL, Antman EM, et al. The physician's role in minimizing pre-hospital delay in patients at high risk for acute myocardial infarction: recommendations from the National Heart Attack Alert Program. Working Group on Educational Strategies to Prevent Prehospital Delay in Patients at High Risk for Acute Myocardial Infarction. *Ann Intern Med* 1997;126:645-651.