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

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Background

STI registry is a leading cause of death in the United States and the Western World [1]. Early detection and patient alerting of coronary ischemia or signs of plaque rupture while on ambulation or in transit with symptoms onset could allow prompt evaluation and management to improve clinical outcomes [1]. 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 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

Methods

Throughout 12 months of follow-up, five of 17 patients (29%) 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 IT event due to a subendoocardial rupture that was immediately corrected. No device-related events occurred during the study period. With the exception of measurements prior to Emergency Alarms, the ST-Shifting measurements for the study population remained stable and typically displayed a distribution of 30% of healthy patients having some type of ST deviation 24 hours prior to Emergency Alarm (see Fig. 3). There were more diagnostically significant adverse events than expected. In each case the patient rapidly responded to the Emergency Alarm and upon medical evaluation, a culprit lesion was found. Blue bars indicate stenting of culprit lesion found during angiography (see Fig. 3).

Fig 1: A patient’s implanted Guardian® system (AngelMedical, Inc.) with the internal ECG electrode circuitry (green) and the external alarm unit (red). The Guardian is now undergoing a 1,000 patient multi-center randomized study to assess clinical benefit.

Fig 2: Electrogram traces from the second event of Fig 3, showing the patient's baseline from 24 hours before the event and the data that triggered the emergency alarm. ST-shift data for a patient who had two confirmed culprit lesions found. Blue bars indicate stenting of culprit lesions. The DETECT study has demonstrated the ability of the Guardian implantable electrocardiographic monitoring 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 events, with IVUS confirntation of the ruptured plaque site (LAD) for the second event. For each event the patient rapidly responded to the Emergency Alarm and upon medical evaluation, a culprit lesion was found. Blue bars indicate stenting of culprit lesion found during angiography (see Fig. 3).

Fig 3: Simple ST-shift data, (green dots) for heartbeats prior to the emergency alarm and the data that triggered the emergency alarm. The Guardian is now undergoing a 1,000 patient multi-center randomized study to assess clinical benefit.

Conclusions

The DETECT study has demonstrated the ability of the Guardian implantable electrocardiographic monitoring 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 events, with IVUS confirmation of the ruptured plaque site (LAD) for the second event. For each event the patient rapidly responded to the Emergency Alarm and upon medical evaluation, a culprit lesion was found. Blue bars indicate stenting of culprit lesion found during angiography (see Fig. 3).

References