AngelMed Guardian® Case Study

Detection and Confirmation of Occluded RCA and LCX

Negative ST Shift Resulting in PCI

Caution: Investigational device. Limited by United States law to investigational use.

AngelMed®

At the Heart of Prevention

Patient Profile

Male, age 66 (USA, IMD #4098)

History: Coronary artery disease (CAD), peripheral vascular disease (PVD), acute decompensated heart failure, diabetes (type 2), hypertension, and dyslipidemia.

Medications: Ramipril, metoprolol, amlodipine besylate, aspirin, clopidogrel, furosemide, nitroglycerin, simvastatin and spironolactone.

This patient has a history of partial and whole toe amputations and underwent a subcutaneous debridement all attributed to diabetes. In November 2011, doctors delivered a stent to the patient's LCX (2nd obtuse marginal) after presenting with a STEMI. The following month, the patient received his Guardian device.

Alarm

Alarm-to-Door: 64 min
Date: 7 Mar 2013
Time: 9:58 pm
Type: -ST Shift/NonEl-HR

HR at event: Normal
ST Shift: 19.6%
Duration: ~4min
Hospital ECG: Normal
Symptoms: None

Intervention: oxygen, in-hospital monitoring

Event Summary:
While resting quietly at home on the evening of 7 March 2013, the patient's Guardian device issued a See Doctor alert followed shortly by an Emergency alarm. The patient silenced the warnings and immediately called EMS services for transport to the hospital.

Upon arrival at the hospital, about an hour after the alarm, the attending physician ordered blood tests and an ECG. The blood test proved negative for troponin. The ECG showed normal sinus rhythm, no acute ischemia, and demonstrated no significant change from his previous ECG. A two-view chest study was negative. From the time of the Emergency alarm, the patient remained entirely asymptomatic with no complaints of chest pain, palpitations, or dyspnea. The patient received oxygen and was admitted for closer monitoring. The Guardian device was interrogated the following day where the data demonstrated the occurrence of an acute ischemic event. Consequently, the doctor scheduled the patient for an elective catheterization for 11 March and discharged the patient.

Explanation of Guardian Data:
The data from the Guardian device revealed that a pronounced negative ST Shift of -19.6% had occurred, exceeding the patient's negative ischemia threshold of -13%. This event first triggered a See Doctor alert at 9:56pm, while the patient's heart rate was

slightly elevated. Then at 9:58, as his heart rate decreased to the normal range, the Guardian issued the Emergency alarm. The patient's ST Shift level remained excessively depressed for about 4 minutes, after which it returned to its normal range of approximately 0 ± 3%.

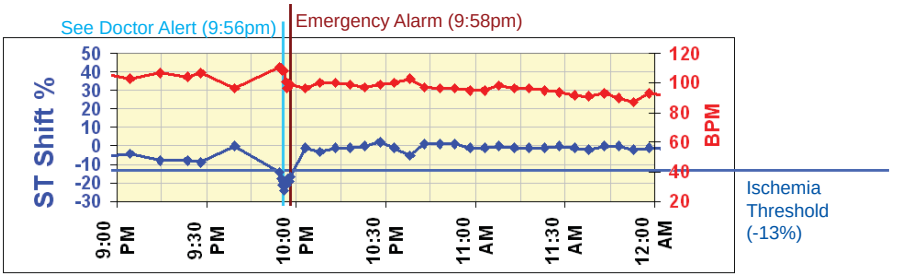

Figure A - ST Shift and Heart Rate at Time of Alarm

The patient's baseline electrogram (EGM), shown in Figure B, was recorded from the day before the Emergency alarm and demonstrates a fairly isoelectric ST segment. Figure C shows the EGM that triggered the Emergency alarm. This EGM clearly reveals a depressed ST segment relative to the patient's baseline EGM - a negative ST Shift.

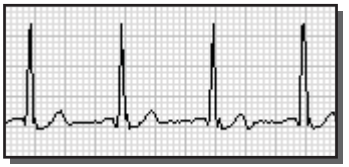

Figure B - Baseline EGM

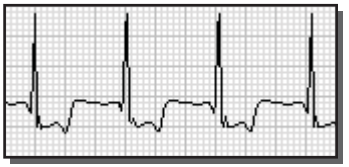

Figure C - Emergency Alarm EGM

Intervention

On 11 March 2013, the patient submitted to a catheterization, where the resulting angiograms revealed two lesions: the culprit one in the proximal RCA (90%) and another in the distal LCX (70%). Both were stented without incident and the patient was subsequently discharged.

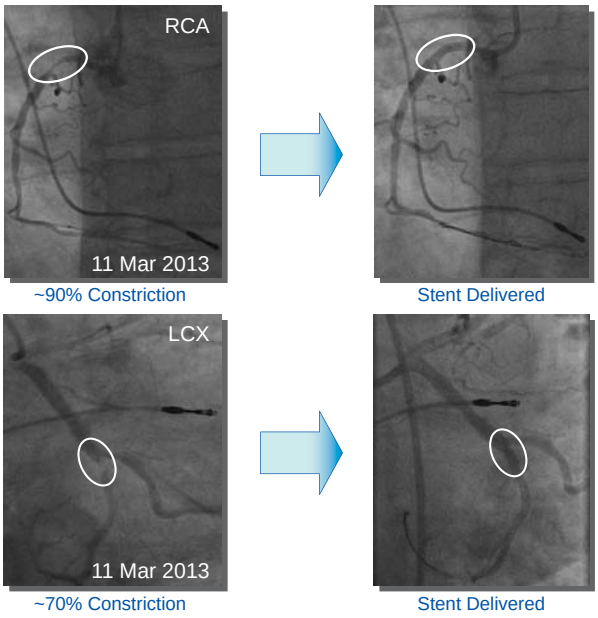

Figure D - Angiograms of RCA and LCX Lesions

Observations & Discussion

The Guardian implant detected an acute change in the patient's ST segment. At the time, the patient was resting quietly and experienced no symptoms. Prompted only by his Guardian device, he called for medical assistance.

At the hospital, conventional cardiac testing indicated no cardiac anomalies, which would have informed the attending physician to discharge the patient immediately. Based on the Guardian data however, the doctor ordered a catheterization which revealed two lesions, both of which were successfully stented.

In this case, it was the Guardian device alone that prompted the patient to seek medical treatment and provided the data that persuaded doctors to conduct the angiography that exposed the two coronary lesions.

AngelMed®
Angel Medical Systems, Inc.
1163 Shrewsbury Ave, Suite E
Shrewsbury, NJ 07702
www.angel-med.com