

# AngelMed Guardian<sup>®</sup> Case Study

## Detection of Acute Ischemic Event

ST Elevation Resulting in PCI



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



*At the Heart of Prevention*

## Patient Profile

Female, age 71 (USA, IMD #2894)

History – Multivascular CAD, hypertension, hyperlipoproteinemia, unstable angina, and diabetes (Type II). Patient has a family history of premature heart disease, sustained a prior heart attack, and received a stent in the ostium of the RCA. Current medications include clopidogrel, lovastatin, aspirin, fenofibrate, beta blocker (nebivolol), Trilipix, triamterene/HCTZ, nitroglycerin prn. Additional medications for the treatment of diabetes.

Doctors originally implanted the Guardian on 29 Nov 2007. There were no alerts for 3.5 years until the implant issued a See Doctor alert to replace the device due to battery depletion. On 5 Jan 2011, doctors replaced the device and discharged the patient without incident.

## Alert

Alarm-to-Door: 58min  
Type: +ST Shift/non-EL HR  
Date: 16 Aug 2012  
Time: 8:22 am

HR at event: Normal  
ST Shift: 27.4%  
Duration: ~ 90min  
Hospital ECG: Normal  
Symptoms: Minor

Intervention:  
catheterization

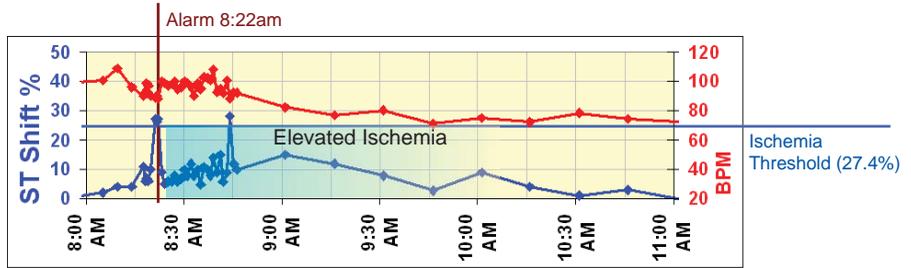
## Event Summary:

While teaching on the morning of 16 Aug 2012, the patient's Guardian device issued an Emergency alarm. Rather than call for an ambulance, the patient opted for a family member to take her to the hospital. At the time of the alarm, she was asymptomatic, but experienced some back pain and nausea on her trip to the hospital. Upon arrival, the attending physician ordered standard ECG and blood tests. The ECG was negative as were the blood enzyme levels (Troponin 0.01, CK-MB 1.9, Total CPK 88) - demonstrating no indication of cardiac injury or necrosis.

Doctors retrieved data from the Guardian IMD, which revealed that the Guardian device detected an acute ischemic event at the time of the alarm. As a consequence, doctors admitted the patient and scheduled her for a cardiac catheterization the following day.

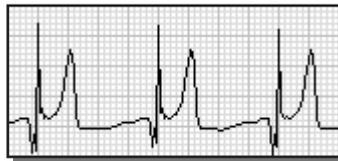
## Explanation of Guardian Data:

The Guardian data, shown in Figure A, demonstrate that at 8:22am a positive ST Shift event occurred while the patient's heart rate was in the normal range, indicating an acute ischemic event. The ST Shift was measured to be 27.4%, which exceeded the 25% ischemia threshold and was significantly greater than the typical ST Shift variation for this patient, which ranged between -4% and +6%.



**Figure A - ST Shift and Heart Rate at Alarm**

The initial ST Shift spike lasted about 1.5 minutes before moderating to still-elevated levels. Twenty-two minutes later, the ST Shift level spiked again briefly above the ischemia threshold and remained at elevated levels for over an hour.



**Figure B - Baseline ECG**



**Figure C - Emergency Alarm ECG**

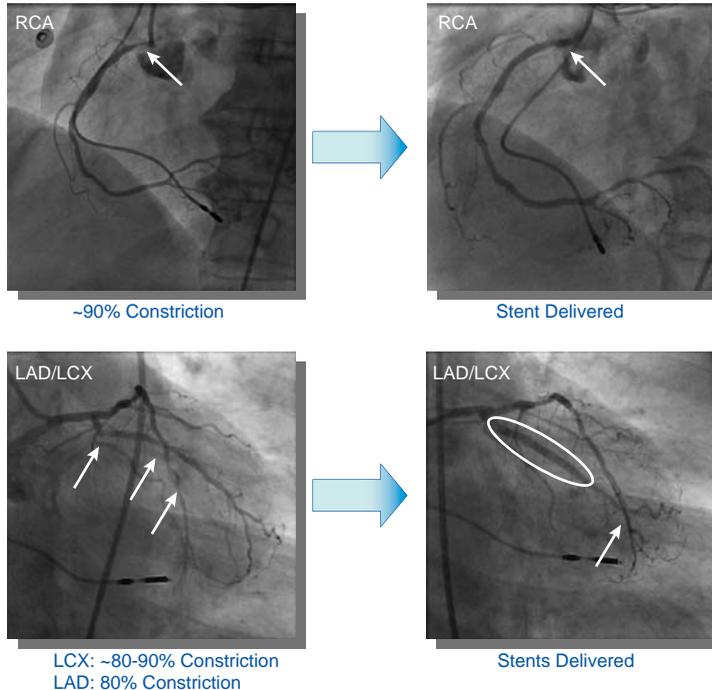
Figure B shows an electrogram of the hourly baseline in effect at the time of the alarm. Figure C shows the electrogram that triggered the alarm. The advancement of the T-wave raises the average voltage value of the ST segment enough to exceed the patient's ischemia threshold and cause the alarm.

## Intervention

The catheterization identified:

- ◆ a 90% focal stenosis of the previously placed RCA stent
- ◆ several de novo lesions in the LCX, resulting in 80-90% narrowing
- ◆ another lesion in the apical LAD, resulting in 80% stenosis

The doctor administered balloon angioplasty to the RCA stent. He then opened the LCX using three overlapping drug eluting stents and delivered another drug eluting stent to the LAD.



**Figure D - Multi-Vessel Lesions**

## Observations & Discussion

Although the patient was initially asymptomatic, the Guardian device alarm prompted her to seek immediate medical treatment. At the hospital, conventional standard-of-care tests were negative and suggested no acute ischemia.

The Guardian device data however, showed two distinct acute ischemic events, with atypically elevated ischemia demonstrated over the course of about 90 minutes. These data persuaded the doctor to order catheterization, which revealed the multivascular stenosis and led to subsequent remedial treatment via PCI.