

AngelMed Guardian[®] Case Study

Detection of Demand-Induced Persistent Ischemia

Prolonged ST Depression Resulting in LCX Stent



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



At the Heart of Prevention

Patient Profile

Latin-American male, age 69 (Brazil, IMD #158)

History - Hypertension and dyslipidemia requiring medication

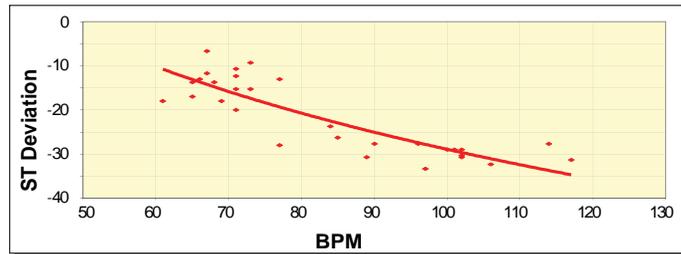
The patient had a previous revascularization in 2000 and prior to implantation had angina CCAS II. He also had stenoses in both RCA and LCX, demonstrating nearly 3 mm of ST depression on his surface ECG during stress testing. The Guardian device was implanted without incidence. It was decided to stent both the RCA and LCX, but to stage the procedures and stent the RCA first .

RCA Stent

Prior to the RCA PCI procedure the patient's beta blocker dose was reduced and his heart rate elevated as a result. This response was captured by the Guardian device EGM tracings.



The device also captured the corresponding ST deviation data (Figure A), which showed a direct relation between the magnitude of ST Deviation and the patient's heart rate.



On 29-Apr the RCA stent was delivered and the patient was later discharged.

Alarm

Date: 6 May 2006
Time: 9:38 am

HR at event: Elevated
ST Shift: 43%
Duration: ~60 min

Intervention:
LCX stent

Event Summary:

Six days after being discharged, the patient experienced a series of four See Dr. alerts (ST shift at elevated heart rate) starting at 9:10 am. (By design, only the first alert signaled the patient.) The last alert escalated into an emergency alarm at 9:38 am when the condition (ST Shift > 41%) persisted for more than 10 consecutive minutes. Figure B shows the timing of the alarms and the corresponding ST shift and heart rates.

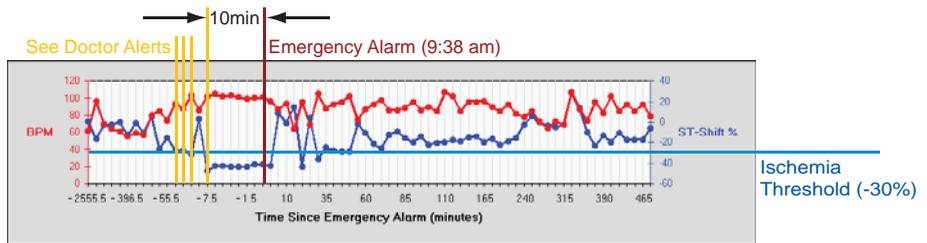


Figure B - ST Shift and Heart Rate

The data in the figure demonstrate that the patient's ST deviation increased significantly as his heart rate rose. The following histograms illustrate this point more clearly. The histograms plot the ST deviation distributions, captured with each heartbeat by the Guardian device, across five heart rate ranges; Normal plus four increasingly Elevated grade ranges. The distributions show a decisive shift to the left - away from zero - as the heart rate increases: indicative of rate-induced ischemia.

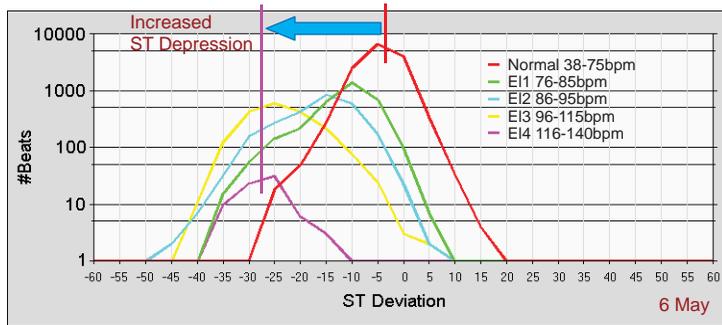


Figure C - Pre-Stent ST Depression Increasing with HR

On May 10, the patient underwent his 2nd PCI procedure to treat the remaining LCX lesion. The following day, the histogram data retrieved from the IMD showed a fairly uniform distribution around the isoelectric point, which did not vary with heart rate.

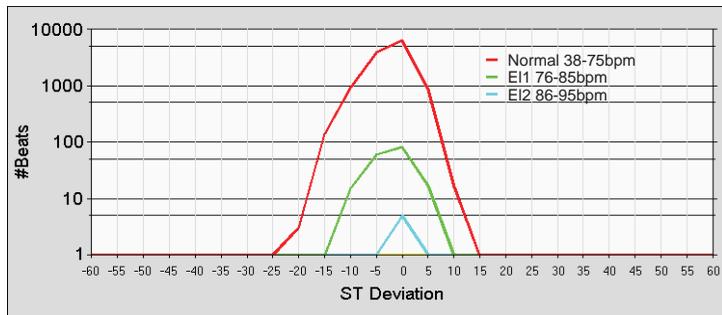


Figure D - Post-Stent ST Depression Minimal and Stable with HR

Intervention

Histogram data from 11 months later (Figure E) show a minor shift of the histogram envelopes relative to heart rate, but still greatly reduced from that shown in Figure C.

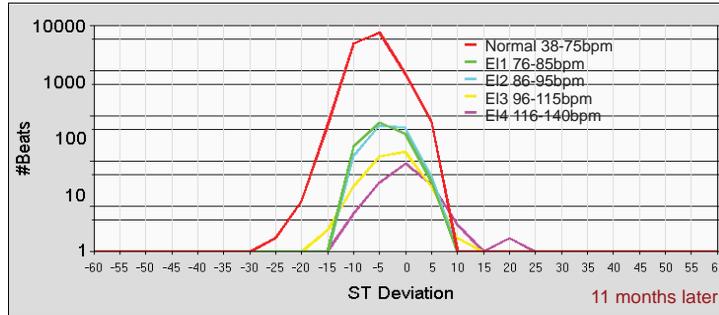


Figure E -
Post-Stent
Minimal ST
Depression

Observations & Discussion

This patient had two known lesions that induced a progressive ST segment depression as his heart rate increased. The AngelMed Guardian device alerted the patient when his ST segment shift became excessive and it also informed him via Emergency alarm that the condition persisted for a prolonged time period, thereby causing him to seek medical attention.

In the hospital, data retrieved from the implant showed pre- and post-stent ST deviation histograms that demonstrated a marked correction in the patient's demand-based ischemia.