

AngelMed Guardian[®] Case Study

Detection and Confirmation of Progressive Plaque Burden

ST Trend Alert Resulting in Stent



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



At the Heart of Prevention

Patient Profile

Male, age 65 (Brazil, IMD #2326)

History – Vascular diseases including PAOD, CAOD, and CAD. Patient has sustained three heart attacks, undergone coronary bypass (CABG) surgery, and had six stents placed on different occasions. He has occasional persistent precordial pain. Current medications includes clopidogrel, simvastatin, aspirin, trimetazidine, mononitrate, nifedipine oros, metoprolol.

Doctors implanted the Guardian on 15 June 2010 without incident and the patient was discharged the following day.

Alert

Alarm-to-Door: N/A
Type: ST Trending
Date: 9 Dec 2010
Time: 9:00 am

HR at event: Normal
ST Shift: N/A
Duration: N/A
Hospital ECG: Normal
Symptoms: None

Intervention:
catheterization

Event Summary:

On the morning of 9 Dec 2010, the Guardian device signaled the patient with a See Doctor alert, the less severe of the two Guardian warnings. He had no symptoms. The patient contacted his doctor who advised him to report to the hospital, where he presented later that morning. Upon arrival, doctors retrieved data from the IMD, which revealed that the Guardian device detected an ST Deviation Trending event - an event that suggests the existence of progressive coronary artery stenosis.

Acting on the data, doctors scheduled the patient for a cardiac catheterization, the following week.

Explanation of Guardian Data:

The ST Deviation Trending histogram, downloaded from the patient's IMD and shown in Figure A, provides about a five-month history of the patient's median daily ST deviation. (Once a day, the Guardian calculates the median daily ST deviation from all the heartbeats that it characterized over the previous 24 hours.) His IMD was programmed to declare a Trending event when the lowest and highest median daily ST deviations, over the long-term trending period differed, by over 20.

For the five-month period, the patient's median daily ST deviation, an ST depression in this case, initially drifted more negative to -25 and then abruptly turned positive. The positive trend persisted with few exceptions up to the morning of the alert when the median daily ST deviation rose to -4, thereby exceeding the threshold of 20.

EGMs downloaded from the patient's IMD near the start and end of the trending time period also demonstrate how ST deviation changed.

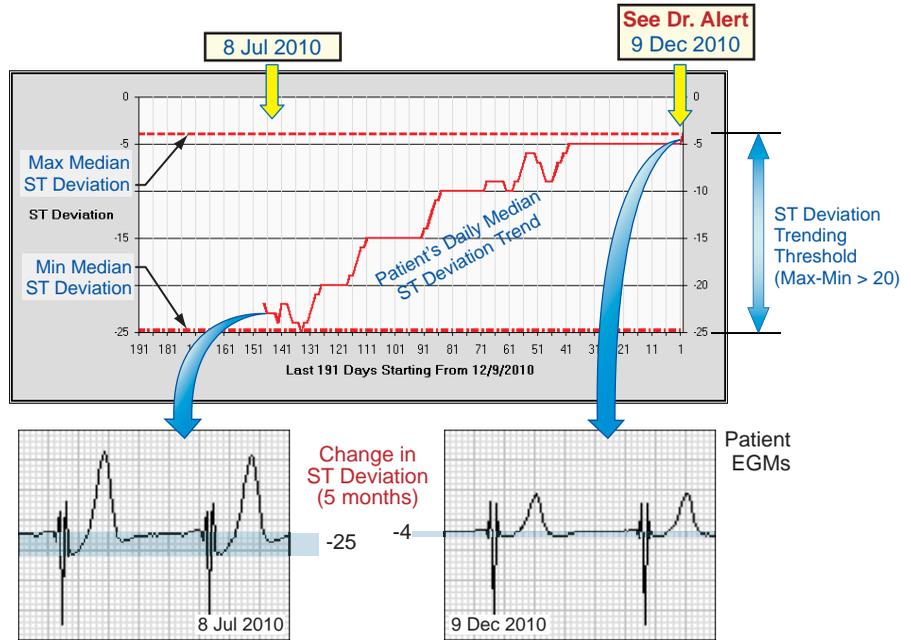


Figure A - ST Deviation Trending Histogram and Corresponding EGMs

Intervention

The catheterization identified a lesion progression in the RCA proximal to the bypass graft. An angiogram taken in May 2010, about seven months earlier, shows the occlusion to be at about 40%. By the time of the catheterization, the lesion had progressed to between 80% and 90%. Doctors delivered a drug-eluting stent to restore the arterial opening.

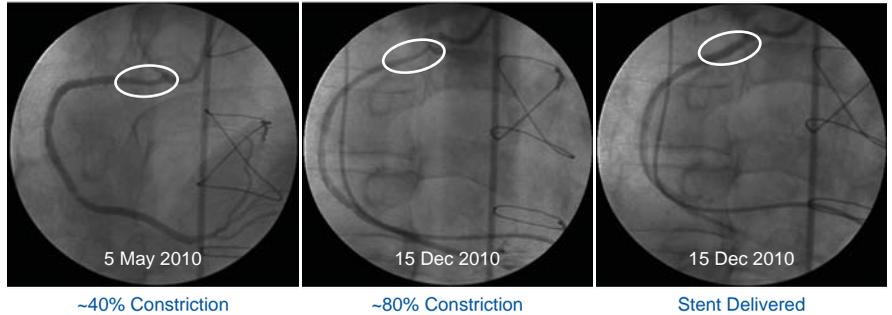


Figure B - Plaque Burden, Progression and Resolution

Observations & Discussion

The bypass graft lesion grew substantially over a five-month period without causing symptoms that might have prompted the patient to see his doctor. The Guardian device however, tracked the slowly progressive change in the patient's median daily ST deviation and alerted him when the change exceeded the ST Trending threshold.

At the hospital, the Guardian data convinced doctors to investigate further with catheterization, which located the plaque progression and ultimately led to successful stenting.