

AngelMed Guardian[®] Case Study

Detection and Confirmation of Progressive Plaque Burden

ST Depression Resulting in Stent



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



At the Heart of Prevention

Patient Profile

Male, age 53 (Brazil, IMD #952)

History – Hypertension, diabetes, and dyslipidemia with treatment consisting of aspirin, atendol (beta blocker), clopidogrel, simvastatine, and anlodipina (amlodipine).

The patient has a history of arterial occlusion formation and revascularizations consisting of an LCX stent in 2006 as well as a collateralized RCA occlusion, which remains untreated. He was implanted on 3 May 2006, before receiving his LCX stent.

Alarm 1

Alarm-to-Door: 150 min
Date: 14 Jun 2010
Time: 7:07 am

HR at event: Normal
ST Shift: ~-22%
Duration: >8 hrs
Hospital ECG: Normal
Symptoms: None

Intervention: heparin,
in-hospital monitoring

Event Summary:

While preparing for World Cup festivities on the evening of 13 Jun 2010, the patient received a series of See Doctor alerts from the Guardian IMD. The next morning, having experienced no symptoms, the patient awoke to an Emergency alarm and arranged transportation to the hospital, a trip that would require over 2 hours.

At the hospital, the attending physician ordered an ECG and checked the patient's troponin levels; both tests proved negative. Nonetheless, the Guardian showed a pronounced and persistent ST shift. In response, the doctor admitted the patient to be monitored and administered heparin.

Explanation of Guardian Data:

Although the patient historically experienced an ST Shift daily variation of $2 \pm 2\%$, in the hours preceding the first Emergency alarm, the Guardian recorded a significant negative ST Shift ($\geq -21\%$) with Elevated heart rate and issued See Doctor alerts. This negative trend continued through the evening. At 7:07 the following morning, the Guardian recorded a significant negative ST Shift this time with Normal heart rate and issued an Emergency alarm. The ST Shift trended even lower over the ensuing 8 hours.

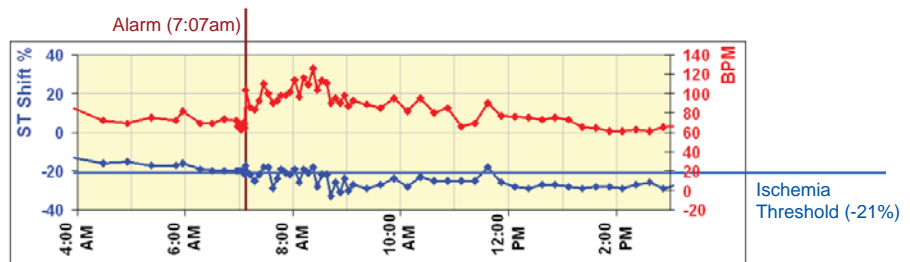


Figure A - ST Shift and Heart Rate, Alarm 1

Figure B shows the baseline electrogram (EGM) captured from the day prior to the event. Figure C shows the EGM that triggered the alarm. Clearly visible is a pronounced negative ST shift with an inverted T wave.



Figure B - Baseline EGM

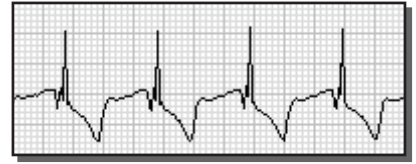


Figure C - Emergency Alarm EGM

Over the following days, the Guardian would issue more alarms.

Alarms 2 & 3

Alarm-to-Door: 0 min
(in hospital)

Date: 14 Jun 2010 (Alm2)

Time: 3:10 pm

Date: 15 Jun 2010 (Alm3)

Time: 7:25am

HR at event: Normal

ST Shift: -26.6% (Alm2),

-23.4% (Alm3)

Hospital ECG: Normal

Intervention: heparin,
in-hospital monitoring

Event Summary:

Throughout the day following admission, the patient's ST segment was chronically depressed. At 3:10pm and again the following morning at 7:25am, the Guardian issued two additional Emergency alarms, again for a negative ST Shift at Normal heart rate. Still, surface ECG showed no anomalies and the troponin levels remained in the normal range.

Explanation of Guardian Data:

At the times of the second and third alarms, the Guardian recorded negative ST-shifts of 26.6% and 23.4%, respectively. Figure D shows the ST-Shift% and heart rate for the two days over which these events unfolded. Although surface ECG data were nominal, the EGM data clearly reveal a persistent, negative ST Shift.

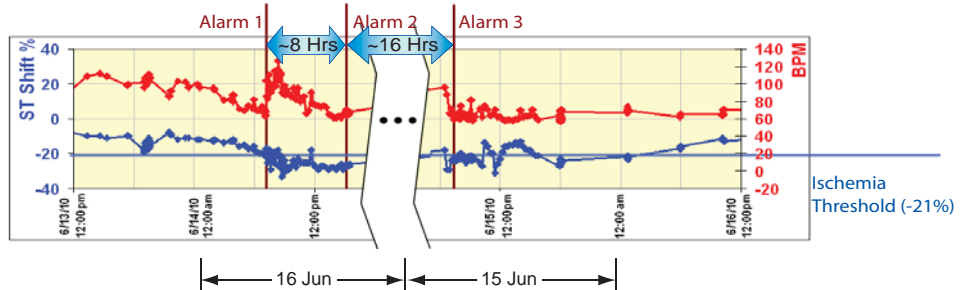


Figure D - ST Shift and Heart Rate, All Alarms

Figure E displays the patient's baseline electrogram showing no apparent ST segment displacement. Figures F and G display the EGMs at the times of the second and third alarms, clearly revealing a negative ST-shift with T-wave inversion.



Figure E - Baseline EGM



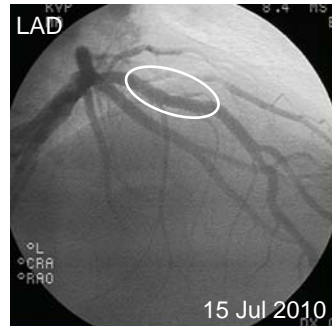
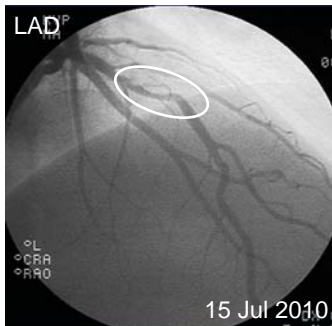
Figure F - Alarm #2 EGM



Figure G - Alarm #3 EGM

Intervention

The second alarm (Alarm 2), prompted doctors to order a cardiac angiography that revealed a large progression in the severity of the lesion in the proximal portion of the LAD. An IVUS confirmed a plaque burden of 74%, which doctors successfully stented.



Observations & Discussion

The Guardian contributed to this patient's well-being by:

- ♦ prompting him to seek medical treatment
- ♦ informing the physicians of a progressive coronary occlusion

The alarm prompted the patient to seek medical attention, which he would not have done since he was asymptomatic.

At the hospital, surface ECG and troponin levels proved negative; however, the EGM data showed a decisive ST shift. Consequently, physicians determined to hold the patient for observation and administer prophylactic medication. Subsequent alarming prompted further testing that confirmed the plaque progression and led to successful remediative stenting.