

AngelMed Guardian[®] Case Study

Rapid Detection and Confirmation of Occluded RCA Due to Ruptured Plaque

ST Elevation Resulting in Stent
Alarm-to-Door: 6 minutes



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



At the Heart of Prevention

Patient Profile

Latin-American male, age 65 (Brazil, IMD #164)

History - Hypertension and dyslipidemia

Patient had new onset angina (CCAS II) due to a 70% mid LAD lesion, associated with a positive exercise test (2-3 mm ST depression at peak exercise). The patient underwent elective stent placement in the LAD one week following device implantation.

Alarm 1

Alarm-to-Door: 6 min
Date: 29 Nov 2007
Time: 12:09pm

HR at event: Normal
ST Shift: 31.3%
Duration: ~70 min
Surface ECG: Normal

Intervention: aspirin,
heparin,
in-hospital monitoring

Event Summary:

Eighteen months later, an Emergency alarm occurred, while he was picking up medication at the hospital. At this time, the patient experienced minimal symptoms. The patient was admitted for observation and given aspirin and intravenous unfractionated heparin. Surface ECG was also applied, but revealed no ST segment elevation. At 12:27 pm, data was retrieved from his AngelMed Guardian device.

Explanation of Guardian Data:

For the 24-hour period prior to the alarm, the patient's ST-Shift% values maintained a range of about -7% to +11%. The ischemia detection thresholds were set at $\pm 30\%$. At 12:09 pm, the Guardian device issued an Emergency alarm. Subsequent review of the Guardian EGM data revealed that the patient experienced a significant positive ST shift of 31.3% at 59 bpm, which was in the normal range for this patient. The ST segment elevation persisted for about one hour before resolving. (From the retrieved Guardian data, it was determined that by the time the ECG was administered, the ST elevation had been resolved.)

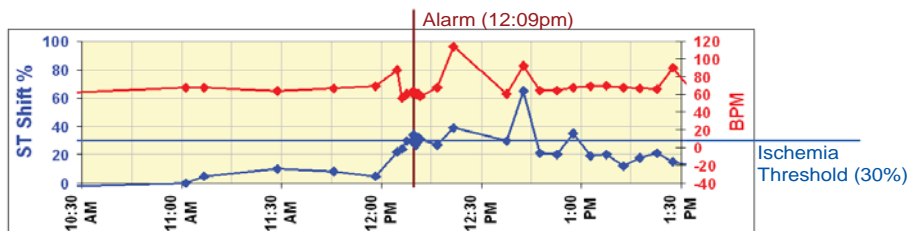


Figure A - ST Shift and Heart Rate, Alarm 1

Figure A shows the ST-Shift% and heart rate plot at the time surrounding the event. At the time of the alarm, the patient's heart rate was normal, although it rose temporarily in response to the device's alarm signal.

Figure B shows the baseline electrogram captured from the day before the event. It reveals that this patient generally has no ST elevation. Figure C shows the positive ST shift, relative to the baseline, that triggered the Emergency alarm.



Figure B - Baseline EGM



Figure C - Emergency Alarm 1 EGM

Alarm 2

Alarm-to-Door: 0 min
(in hospital)
Date: 29 Nov 2007
Time: 9:24 pm

HR at event: Normal
ST Shift: 31.3%
Duration: ~2 hrs
Surface ECG: N/A
Intervention: heparin,
angiography, IVUS,
stent

Event Summary:

About nine hours later, a second Emergency alarm occurred due to recurrent ST elevation which resolved over the next 2 hours. The patient had no symptoms during this time period.

Explanation of Guardian Data:

The Guardian EGM data showed that at 9:24 pm the patient had had a significant positive ST shift (31.3%) at 69 bpm, increasing to over 36%. (His ST levels in the previous 4 hours ranged from approximately 4 to 15). Figure D shows the ST-Shift% and heart rate plot at the time surrounding the second event.

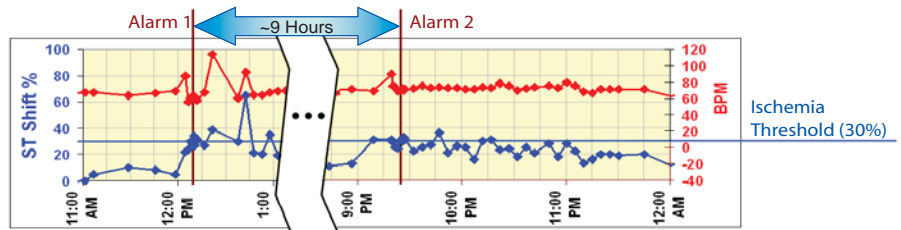


Figure D - ST Shift and Heart Rate, Alarm 2

Figure E presents the baseline electrogram from the day before the second alarm and shows the patient's usual slight ST elevation. Figure F shows the positive ST shift that triggered the alarm.



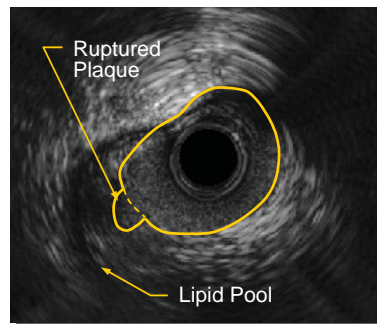
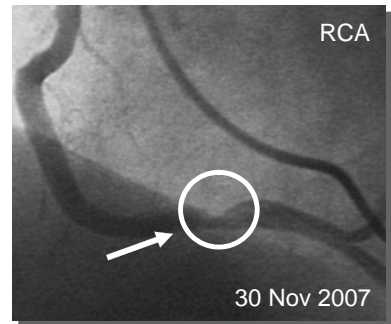
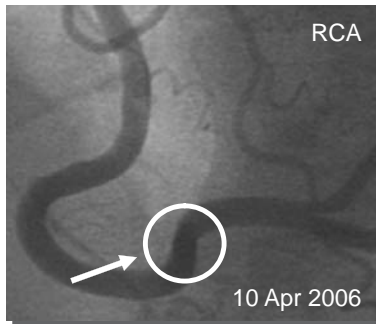
Figure E - Baseline EGM



Figure F - Emergency Alarm 2 EGM

Intervention

In response to the second event, the patient was given a cardiac angiography, where a significant ruptured plaque site was found in the patient's dominant right coronary artery (RCA), compared to the prior angiography. IVUS confirmed the presence of the ruptured plaque site. The lesion was subsequently stented and the patient then discharged.



Observations & Discussion

The AngelMed Guardian device detected and recorded definitive ST segment changes at the time of the alarm, something the surface ECG could not do because of the transient nature of the episode. The Guardian data prompted doctors to hold the patient for further observation, administer prophylactic medication, which likely aided the patient during the second event, and enabled them to identify and treat an acute lesion.