

AngelMed Guardian[®] Case Study

Rapid Detection and Confirmation of Occluded LCX Due to Ruptured Plaque

ST Elevation Resulting in CABG
Alarm-to-Door: 60 minutes



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



At the Heart of Prevention

Patient Profile

Latin-American post-menopausal female, age 52 (Brazil, IMD #338)

History - Diabetes, hypertension and hyperlipidemia

Patient had unstable angina due to a 70% stenosis of the proximal, right coronary artery (RCA). She was implanted on 15 Mar 2007, stented (RCA) four days later, and subsequently discharged.

Alarm 1

Alarm-to-Door: 60 min
Date: 17 Sep 2007
Time: 12:20 pm

HR at event: Normal
ST Shift: 39.2%
Duration: ~15 min
Hospital ECG: Normal

Intervention: heparin,
clopidogrel,
in-hospital monitoring

Event Summary:

About 6 months later, the patient presented to the hospital 60 minutes after an Emergency alarm (ST elevation at normal HR) had occurred. At the time of the alarm, she felt ill and had chest pain, which resolved about 20 minutes later. Upon arrival, she had no symptoms and her admission troponin levels and 12-lead ECG were normal. At 1:45 pm, data was retrieved from her AngelMed Guardian device. The patient was subsequently admitted for in-hospital monitoring and administered intravenous unfractionated heparin and clopidogrel.

Explanation of Guardian Data:

Prior to the alarm, the patient's ST-Shift% values maintained a range of -7.6% to +14.3%. The ischemia detection thresholds were set at +25% and -22%. At 12:20 pm, the Guardian EGM data shows that the patient had a significant positive ST shift of 39.2% at 72 bpm, which triggered the alarm. Within 15-20 minutes the elevation had abated.

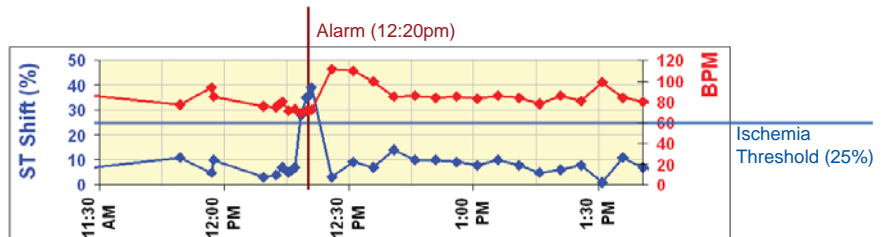


Figure A - ST Shift and Heart Rate, Alarm 1

Figure A shows the ST-Shift% and heart rate plot at the time surrounding the event. The heart rate, though normal at the time of the alarm, rose abruptly in response to the patient's reaction to the alarm signal.

Figure B shows the baseline electrogram captured from the day before the event. It demonstrates a slight ST elevation, which is typical for this patient. Figure C shows the positive ST shift that triggered the Emergency alarm.



Figure B - Baseline EGM



Figure C - Emergency Alarm EGM

Alarm 2

Alarm-to-Door: 0 min
(in hospital)
Date: 18 Sep 2007
Time: 12:06 am

HR at event: Normal
ST Shift: 29.2%
Duration: ~30 min
Hospital ECG: Normal

Intervention: angiography,
IVUS,
coronary bypass

Event Summary:

That night the patient had a recurrent episode of chest pain greater than that experienced during the first event. This was accompanied by a second Emergency alarm. Of note, the simultaneous 12-lead surface ECG showed little change from the prior period, and the troponin levels remained within normal limits.

Explanation of Guardian Data:

The Guardian EGM data showed that at 12:06 am the patient had had a significant positive ST shift (28.2%) at 69 bpm. (Her prior 1-to-12 hour range was -4.8 to +10.6). Figure D shows the ST-Shift% and heart rate plot at the time surrounding the second event.

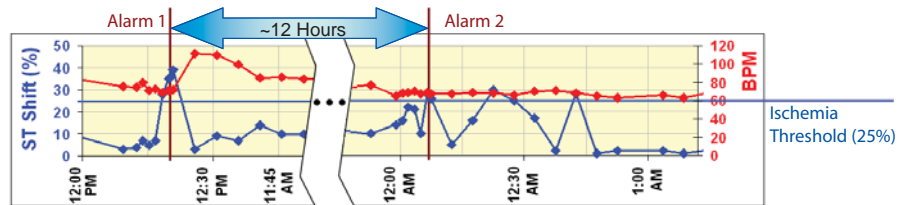


Figure D - ST Shift and Heart Rate, Alarm 2

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

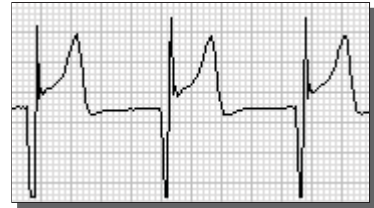
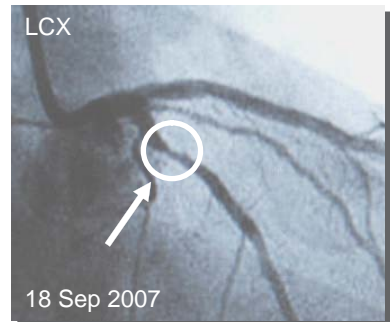
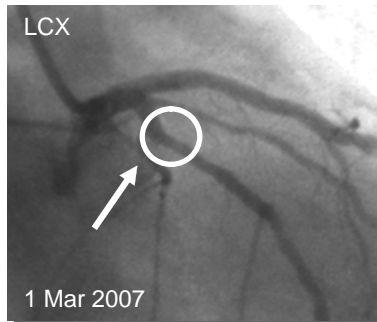


Figure F - Emergency Alarm EGM

Intervention

The second event prompted cardiac angiography, which revealed a large increase in the severity of the lesion in the proximal portion of the left circumflex, compared to the prior angiography. IVUS confirmed the presence of a ruptured plaque. Four days after the second alarm, the patient underwent successful bypass surgery.



Observations & Discussion

The alarm-to-door time of 60 minutes is significantly shorter than the 2.5-to-3 hour period reported in the literature. And, while the surface ECGs showed no abnormalities, the AngelMed Guardian device detected and recorded definitive ST segment changes at the time of the alarm, which prompted doctors to hold the patient for observation. In-hospital monitoring with prophylactic medication likely provided benefit to this patient during the second event.