

AngelMed Guardian[®] Case Study

Detection and Confirmation of Occluded LAD

ST Elevation Resulting in CABG Surgery



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



At the Heart of Prevention

Patient Profile

Male, age 47 (Brazil, IMD #2662)

History: Smoker, arterial hypertension, coronary artery disease (CAD) with history of angioplasty with stent implant.

Medications: atenolol, capoten, simvastatin and aspirin.

In June 2010, the patient presented with an acute myocardial infarction (AMI) characterized by positive ST elevation. Doctors administered streptokinase and performed a cardiac catheterization, which showed an occlusion in the circumflex artery (LCX) at the mid-third and an 80% lesion in the proximal third of the anterior descending artery (LAD). Doctors then performed a rescue angioplasty and delivered a stent to the LCX. Two months later in Aug 2010, the patient received his Guardian implant and was discharged the following day.

Alarm

Alarm-to-Door: ~80 min

Date: 12 Oct 2010

Time: 2:37 pm

Type: +ST Shift/NonEI-HR

HR at event: Normal

ST Shift: 19.8%

Duration: <2min

Hospital ECG: Normal

Symptoms: None

Intervention: heparin,
aspirin, streptokinase,
in-hospital monitoring

Event Summary:

After walking a number of blocks and climbing a flight of stairs on the afternoon of 12 Oct 2010, the patient's Guardian IMD sounded an Emergency alarm. Although entirely asymptomatic, the patient immediately left for the hospital.

Upon arrival at the hospital, the physician on-call ordered diagnostic tests that showed elevated troponin levels; however, the CPK and CK-MB were normal as were the ECG results. In addition, data retrieved from the Guardian implant demonstrated that a significant positive ST Shift had occurred at the time of the alarm (see Figure A). Doctors admitted the patient for monitoring and intensified the clinical treatment by administering heparin and aspirin. The patient was scheduled for angiography on 15 Oct.

Explanation of Guardian Data:

Over the prior two-month period during which the Guardian was implanted, the patient's intracardiac ST Shift experienced a typical variation of $0 \pm 5\%$. On the day of the alarm at 2:37pm, the Guardian detected an acute ST segment elevation that exceeded the ST Shift thresholds that had been established for the patient.

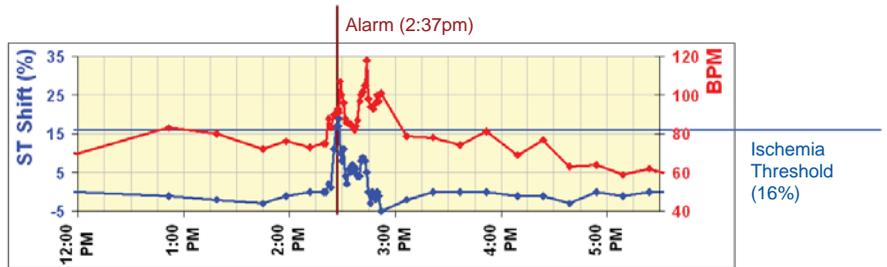


Figure A - ST Shift and Heart Rate at Time of Alarm

And, although the patient's heart rate had slightly increased, likely due to the exertion from climbing the stairs, his heart rate was still in the normal range at the time. Consequently, the Guardian issued a +ST Shift at Non-Elevated Heart Rate event, triggering the Emergency alarm. The patient's ST Shift dropped after approximately 2 minutes, but remained at relatively elevated levels for the next 15 minutes.

Figure B shows the baseline electrogram (EGM) recorded from the day prior to the Emergency alarm. Figure C shows the EGM that triggered the Emergency alarm. This EGM demonstrates an elevated ST segment relative to the patient's baseline EGM - a positive ST Shift.



Figure B - Baseline EGM



Figure C - Emergency Alarm EGM

Intervention

The 15 Oct 2010 angiography revealed an occlusion at the end of the proximal third of the LAD with late and delayed anterograde opacity of the lesion. It was also noted that the LCX stent, implanted 4 months earlier, presented a 50% luminal loss (restenosis) at the distal border.

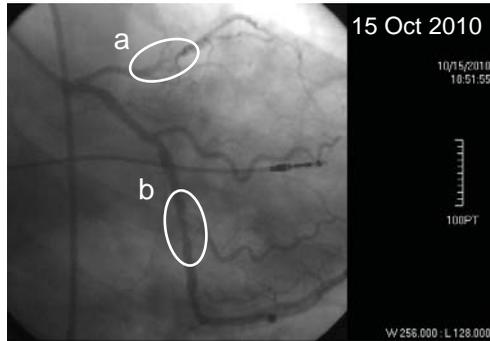


Figure D - LAD and LCX
a) Occlusive LAD lesion
b) Restenosis at LCX stent

In view of these findings, the attending physician scheduled the patient for coronary artery bypass (CABG) surgery, grafting the left internal mammary artery (LIMA) to the LAD. The patient recovered without incident.

Observations & Discussion

The Guardian device detected an abnormal ST-segment change and alerted the patient of the condition. Acting on the alarm, the patient immediately departed for the hospital. Because this patient was entirely asymptomatic, it's unclear when or if he would have sought treatment had he not had the Guardian device.

Although the results from the clinical examination were mixed (elevated troponin, but negative ECG, CPK, CK-MB), the Guardian data demonstrated a rapid and acute ST segment change. Consequently, doctors held the patient for further observation and ultimately conducted a cardiac catheterization. The resulting angiography revealed the culprit LAD lesion and the progression of the atherosclerotic lesion in the LCX.