avertix

As the prevalence of cardiovascular disease continues to challenge global health systems, innovative solutions have become imperative for improving patient outcomes. Modern medicine increasingly relies on integrating real-time data, precision diagnostics, and patient-tailored monitoring technologies to combat these complex conditions. Nowhere is this integration more impactful than in the realm of acute coronary syndromes, where early detection and rapid intervention can mean the difference between life and death.

By leveraging sophisticated algorithms and patient-specific data, such systems are capable of detecting medically meaningful changes in cardiac function—often before the patient themselves are aware of any discomfort or warning signs. One of the most compelling demonstrations of this technology's transformative potential can be seen in the following case, which involves The Guardian® System from Avertix Medical Inc.

Life Saving Detection and Early Presentation to the Emergency Department (ED) for a 99% Left Anterior Descending (LAD) Coronary Artery Occlusion Utilizing The Guardian® System by Avertix Medical

The Guardian® System is designed to continuously acquire, digitize, and analyze 10-second electrograms at intervals between 30 and 90 seconds. The system detects the onset of an acute change from what is normal for each specific patient. This real-time evaluation relies upon statistics which are defined using machine learning algorithms that continuously assess thousands of heartbeats of each patient. This approach enables determination of what is "normal" for each patient, irrespective of the severity of a patients' coronary artery disease. Once "normal" has been determined in this manner, statistically significant deviations from "normal" can be easily detected.

Patient History

The patient is a 55-year-old Caucasian male and former smoker with a history of unstable angina, one previous myocardial infarction (location unspecified), Type 2 diabetes mellitus, dyslipidemia, hypertension, a Canadian Cardiovascular Society Angina Classification of I, and a TIMI Risk Score of 4. The patient has undergone 10 prior reperfusion interventions: 3 PTCA procedures, 4 stent placements, and 3 PTCA & Stent combination procedures.

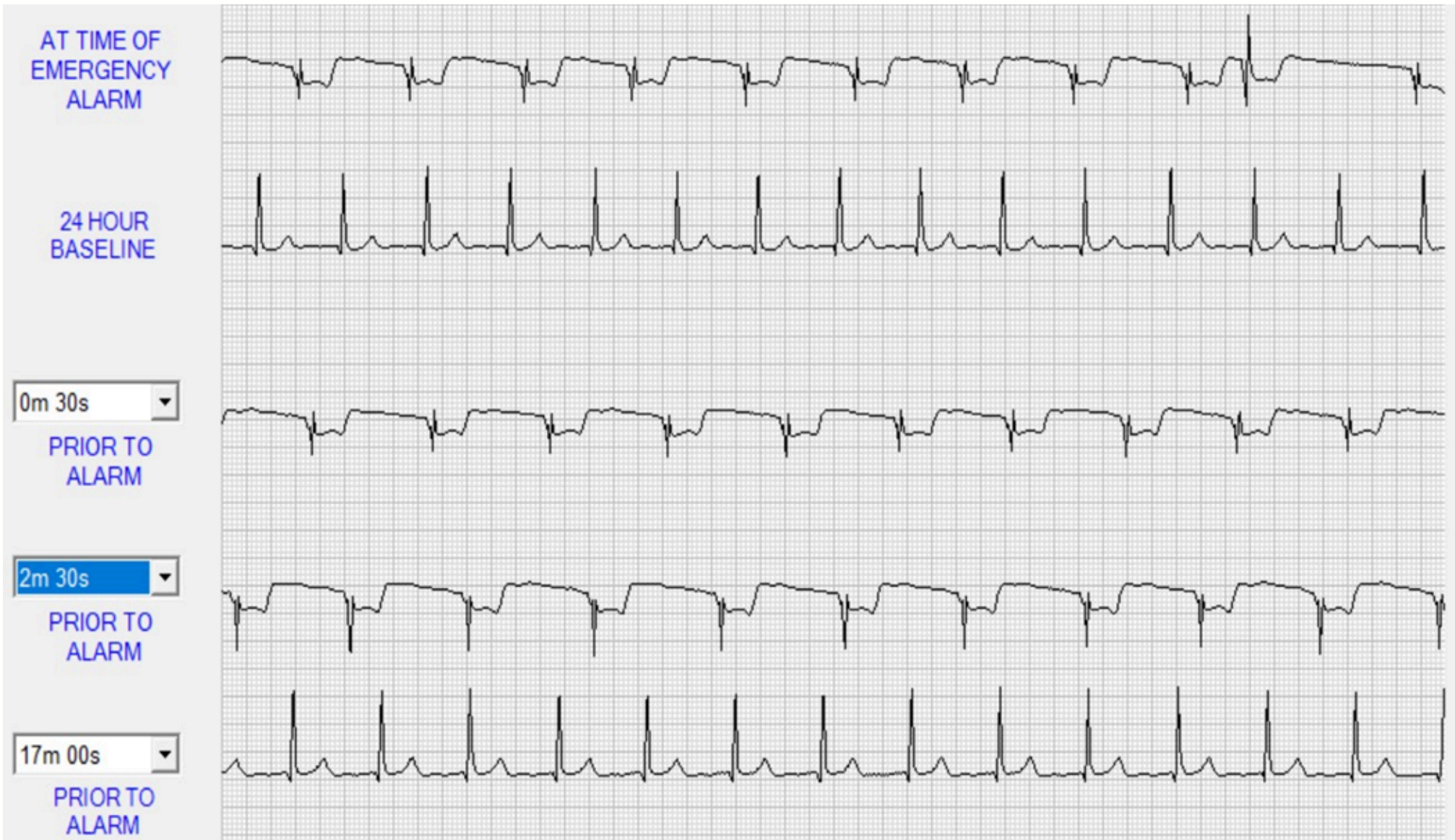
The Guardian System was implanted during a procedure lasting approximately one hour. The Guardian System is currently the only implantable cardiac device that has FDA approval for detecting and alerting patients to coronary occlusions which may lead to recurrent acute coronary syndrome (ACS) events. This patient's cardiovascular history reflects characteristics common among individuals who may receive clinical benefit from the Guardian System due to an increased risk of recurrent ACS events.

Approximately two years following implantation, the Guardian System initiated an Emergency Alarm after detecting a Negative ST Shift at Non-Elevated Heart Rate event. The alarm was accompanied by mild discomfort in the chest, arms, and neck. The patient presented to the ED 36 minutes after the alarm activation. Initial triage revealed ST Segment elevation on a 12-lead ECG and critically increased troponin concentrations. The patient was promptly transferred to the cardiac catheterization laboratory for angiographic assessment of coronary arteries. Angiography identified a significant thrombotic occlusion of the left anterior descending artery, measured at 99.9%. An export catheter was utilized to remove the thrombus, followed by percutaneous transluminal coronary angioplasty (PTCA) and drug-eluting stent placement.

Studies indicate that the Guardian System can reduce patient arrival times by up to eightfold compared to symptom-only presentations (Holmes et al., 2019) and provides more accurate detection of ACS recurrent events than symptoms alone (Gibson et al., 2019). In this instance, the reduced interval between onset of coronary occlusion and subsequent diagnosis and reperfusion, as stated by the attending cardiologist, "very likely saved this patient's life given the magnitude of the LAD occlusion."

Guardian System Electrograms

The following are representative 10-second electrograms obtained from the Guardian System in the period preceding the Emergency Alarm. These samples, which exhibit minimal noise due to the intracardiac lead, reflect typical recordings produced by the Guardian System.



The lowest tracing in the illustration shows the electrogram recorded 17 minutes prior to the alarm, which closely resembles the representative baseline reading (second tracing from the top), with no abnormalities detected. The second tracing from the bottom was taken 2 minutes and 30 seconds before the alarm and demonstrates significant alterations to the QRS complex, notably including ST Segment depression and a marked change in the R wave configuration. These variations persist in all the subsequent electrograms captured before the alarm was triggered (not shown) including the electrogram at 30 seconds prior to the alarm (third tracing from the bottom). Upon reviewing the series of recordings leading up to the Emergency Alarm, the system identifies sustained ST Segment depression relative to a standard 24-hour Baseline.

Prior to issuing an alarm, the system verifies that the presence of ST Segment depression:

- Persists for at least the specified minimum duration.
  - In this instance, the abnormal values for ST shift persisted for over 21 minutes.

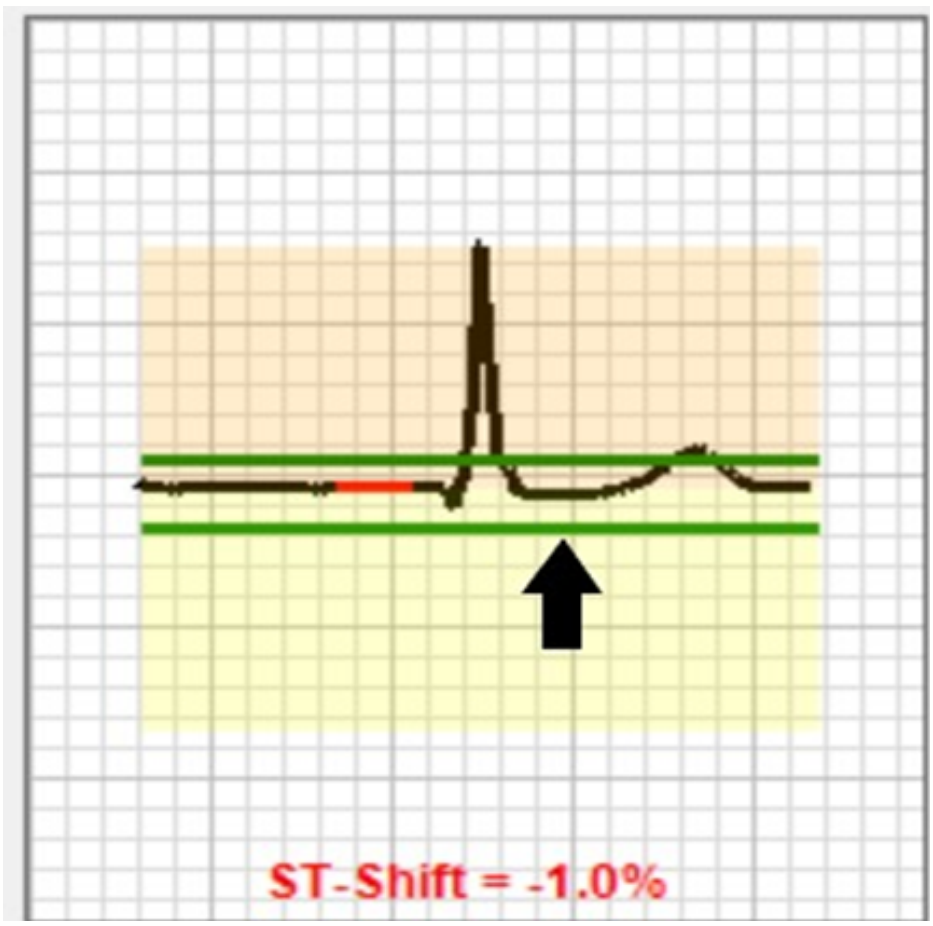
- It is not immediately preceded by an elevated heart rate.
  - The average heart rate prior to the event was 77 bpm.

- Occurs at a non-elevated heart rate and is not attributable to physical activity such as exercise (i.e. the event is a supply-side event and not demand-ischemia); and,
  - The patient was not engaged in exercise prior to the detected event.

- Its magnitude exceeds the machine learning-derived alarm threshold established for the individual patient.
  - The maximum percent of ST Shift reached 27%, surpassing the patient's detection threshold of 17%.

Upon fulfillment of these criteria, the patient received an Emergency Alarm from the Guardian System's internal and external notification mechanisms. As illustrated in the following example, the ST Segment change (indicated by black arrows) is especially evident when contrasting a normal heartbeat (from the baseline electrogram) with one classified as abnormal (from the electrograms that triggered the alarm); in this scenario, the negative alarm threshold (depicted by the lower green line) was exceeded.

[1] Avertix proprietary measure of ST-Segment shift relative to R-wave height



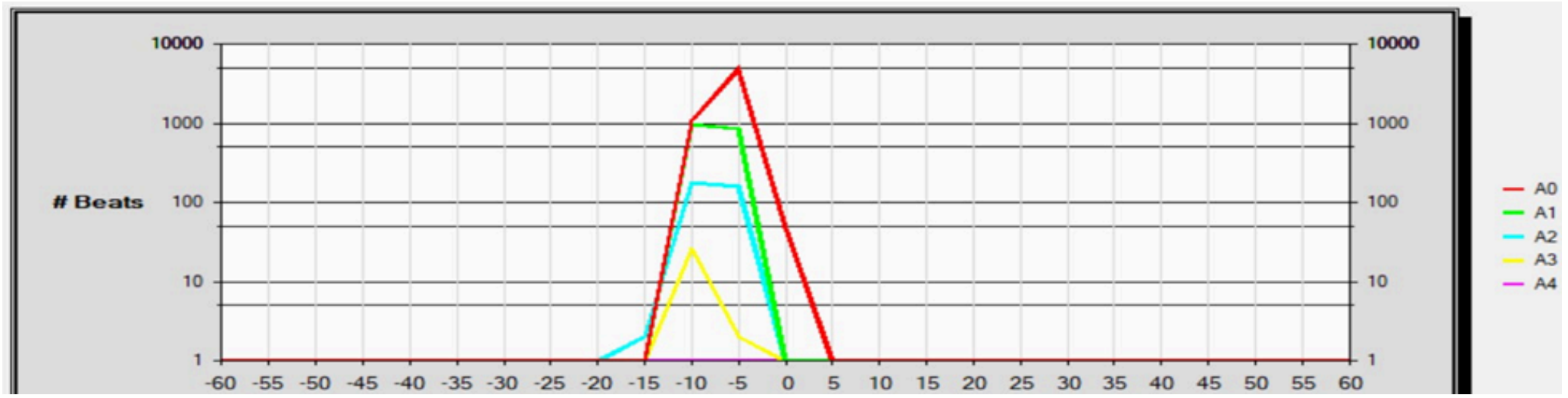
Normal Heartbeat

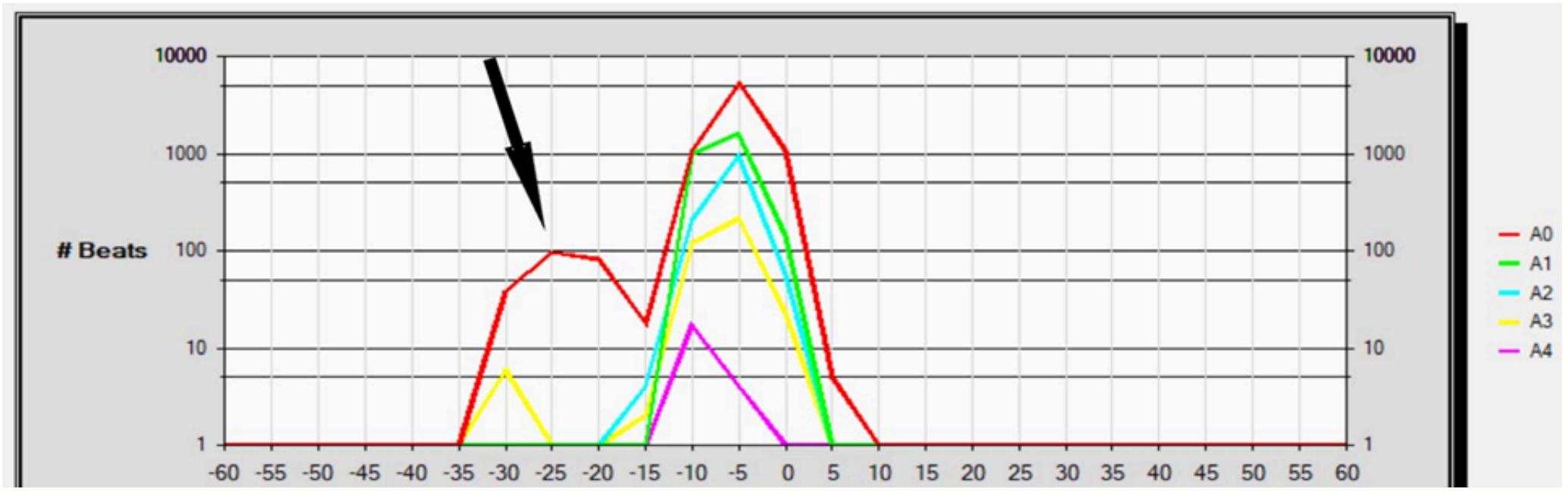
Negative ST Shifted Heartbeat

Another feature of the Guardian System involves ST Segment deviation tracking for each analyzed heartbeat. These data are summarized and stored daily for the prior two-week period. This information shows changes in the cardiac profile of the patient, as a function of heart rate, which can provide additional insight for alarm events. In addition, these data are plotted to detect trends – either elevation or depression – reflecting changes for the patient that may indicate a gradual narrowing of a coronary artery as opposed to the large acute changes covered by an Emergency Alarm.

Below are this patient's daily-histogram examples:

- The histogram plot from the day before the alarm shows ST-Deviations for heartbeats in all heart rate ranges aligned.
- The histogram plot from the day after the alarm displays hundreds of heartbeats with markedly depressed ST Segment deviations (red histogram line area between negative 15 and negative 35 highlighted by the arrow), which resulted from the coronary occlusion.





The Guardian System's Histogram feature mimics daily, ongoing stress testing for patients. Red is the normal / resting (50–90) range; green, turquoise, yellow and purple reflect the ST-deviation histograms for beats categorized into incremental higher ranges up to a maximum of 220 beats-per-minute.

Significance and Technology Highlight

The Guardian System identified an acute thrombotic occlusion of the LAD at normal heart rates in a patient with multi-vessel coronary artery disease. The Emergency Alarm prompted the patient to go to the ED with an alarm-to-door time of 36 minutes. Evaluation at the ED, including cardiac enzyme testing and a 12-lead EKG, confirmed the diagnosis, and subsequent cardiac catheterization revealed a critical 99.9% occlusion of the LAD. The treatment included thrombus removal, PTCA, and successful stent placement.

This case underscores the value of intracardiac continuous ST Segment monitoring, demonstrating that timely intervention can be crucial in preventing fatal events associated with serious thrombotic occlusions of the LAD coronary artery.