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Session Title: Poster Session A

Session Time: Wednesday, May 5, 12:30 pm (Pacific Time)

Session Location: Exhibit Hall (Sapphire I-P)

Initial Results Using an Implantable ST-Segment Monitoring System that Detects and Alerts Patients To Coronary Plaque Rupture and Ischemia

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

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Background: Early warning of acute myocardial infarction (MI) and/or the ST segment changes following vulnerable plaque rupture could allow prompt evaluation and treatment and improve clinical outcomes. We review early findings from the first clinical human studies designed to investigate an implantable ST-segment monitoring system with ischemia detection.

Methods: Ischemia monitors were implanted in 37 patients at high risk for acute coronary syndromes. Continuous monitoring assessed the patients' ST-segment data (from a conventional pacemaker RV apical lead) and detected ischemia when comparisons between ST-segments of sensed data and self-normative reference data from prior 24-hours, exceeded patient-specific ischemia detection thresholds. Ischemia detection caused the implantable monitor and an external "pager" to alert patients to events (e.g., thrombotic coronary occlusion from ruptured vulnerable plaques or heart rate related ST segment shifts from partial coronary obstructions). The patients were trained to recognize and properly respond to Emergency alarms of the monitor (vibration) and pager (beeps/flashing lights) by rapidly seeking medical assistance. Intracardiac data for Emergency alarms during this initial period (58 patient-years of continuous monitoring) were evaluated in relation to conventional measures.

Results: During the follow-up (mean 1.53±0.54 years; median 1.52 years, range 126-974 days) period accurate detection of ruptured plaques using STEMI, angiographic and/or IVUS documentation occurred in 4 patients who showed ST-shifts at normal heart rate ranges. Accurate alerting for heart-rate related ischemic events, reflective of flow-limiting coronary obstructions, also occurred in 4 patients. There were 2 false positive Emergency alerts related to arrhythmias and one due to a programming error. There were no false negative alerts. There were no deaths or Q-wave MIs. The normal range of daily life ST-Segment values was much less (e.g., ST-Shift of 10% of Rwave height) than those during Emergency alarms (e.g. ST-Shift of 45%).

Conclusions: Intracardiac ST-segment shift-based ischemia monitoring appears safe and can provide early warning of (vulnerable) plaque rupture and myocardial infarction. This may be of particular value in high-risk patients, and in patients with "silent" ischemia. Chronic intracardiac ischemia monitoring may reduce symptom-to-door times for patients with recurrent acute coronary syndromes.

Author Disclosures:
C. Michael Gibson: 2 Angel Medical Systems
Alvaro Avezum: 1 Angel Medical Systems
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Tim A. Fischell: 5 Angel Medical Systems, 1 Angel Medical Systems
David R. Fischell: 3 Angel Medical Systems, 4 Angel Medical Systems
Malcolm Foster III: 1 Angel Medical Systems
Richard Kovach: This author has nothing to disclose.
Paulo Medeiros: 1 Angel Medical Systems
Leopoldo Piegas: 1 Angel Medical Systems
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