

InfraReDx enrolls first patient in CANARY trial

By OMAR FORD

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InfraReDx (Burlington, Massachusetts) is testing out a hypothesis in its CANARY (Coronary Assessment by Near-infrared (NIR) of Atherosclerotic Rupture-prone Yellow) trial that could prove beneficial in reducing the rate of peri-procedural heart attacks in patients identified as having high-risk lipid core plaques.

The company took huge steps in proving its theory this week by enrolling the first patient in the multicenter, randomized, open-label Phase 2 trial, which is expected to enroll 108 patients at 10 clinical sites. The trial is expected to use the firm's LipiScan IVUS (intravascular ultrasound) to identify these patients and use Boston Scientific's (Natick Massachusetts) Filter Wire EZ, an embolic protection device, to help reduce the rate of peri-procedural heart attacks.

"[LipiScan IVUS] is an optical diagnostic that is used to assess the chemical composition of the artery wall," Sean Madden PhD, Principle Scientist at InfraReDx told Medical Device Daily. "In particular, what we do is find lipid core plaques using spectroscopy. So the basis of this trial is our first attempt to look at a meaningful outcome for patients that are going into the catheterization lab."

The system includes a cardiac catheter to combine IVUS and near-infrared (NIR) spectroscopy to help cardiologists identify and characterize lipid core coronary plaques. In a single catheter pullback, the LipiScan IVUS provides physicians with a traditional IVUS image that clearly displays key structural parameters of the lesion, including its location, length, degree of stenosis, and plaque burden in addition to confirming proper stent placement.

At the same time, the system performs spectroscopic analysis of optical data to produce a Chemogram map that indicates the location of lipid core plaques and quantifies their lipid core burden. Integrating and co-registering the Chemogram with IVUS provides immediate and valuable information to interventional cardiologists during the cardiac catheterization procedure.

The technology is based on clinical evidence that indicates such heart attacks are caused by disruption by balloon dilation of large lipid core plaques. The contents of these plaques are then carried downstream and occlude the small coronary arteries. LipiScan IVUS can detect the large lipid core plaques most likely to cause this problem, and thereby identify cases in which a distal protection filter might be most effective.

Multiple studies indicate that nearly 10% of patients undergoing PCI experience a heart attack during the stenting procedure.

"Our early data with InfraReDx Lipid Core Plaque detection is finding that if you find a lipid core plaque that is of a very high angular extent and if you inflate the balloon and stent at that site, there's an extremely high risk that plaque will rupture and send its contents down stream," said Madden. "That's a major cause for the peri-procedural infarctions. The CANARY trial is both verifying that hypothesis as well as testing out a potential treatment for that."

He added "so if an interventionalist finds a very large lipid core plaque, such as the one that is over 180 degrees angular extent and at least 4 mm long in a location they are stenting, then those patients will be randomized to the use of what we call an embolic protection device which is basically a filter, and we're using Boston Scientific's EZ filter in this trial."

If the company receives favorable results from the trial it could lead to two potential new label claims, Madden said.

"There are two potential new label claims after the outcome of this trial in future larger trials," he said. "You can kind of view CANARY as the pilot trial that will potentially form a pivotal trial for a new label claim for our device or a new label claim for Boston Scientific's filter."

The company hopes to complete patient recruitment within the next year to 18 months.

The LipiScan IVUS system originally received FDA approval in June 2010 (Medical Device Daily, Sept. 2, 2010). CE mark approval followed, occurring earlier this year (MDD, April 21, 2010).

"We've been quite pleased with the reception the technology has received here in the U.S., where we have been marketing the device since November of last year and we just started marketing the device in Europe, so the first systems are arriving there now," Grant Frazier, VP, Marketing for InfraReDx told MDD. "[In Europe] there's a great deal of interest certainly in the Academic community and we expect fairly rapid adoption of the technology within that segment of the interventional cardiology market. We expect in time it will diffuse down into more general community cardiology centers in Europe. The adoption will follow the same path as it did in the U.S."

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