

Study Shows Safety and Efficacy of Near Infrared Spectroscopy (NIRS) Imaging to Identify Patients and Plaques at an Increased Risk for MACE

Study in The Lancet successfully demonstrated endpoints of identifying both vulnerable patients and vulnerable plaques that are at significantly higher risk for subsequent major adverse cardiovascular events

BEDFORD, Mass., September 27, 2019 –Infraredx, a Nipro Company, a pioneer in intravascular imaging for mapping coronary artery disease, announced that the Lipid-Rich Plaque (LRP) Study was published online today in *The Lancet*. The landmark study demonstrated that near-infrared spectroscopy (NIRS) imaging of non-obstructive areas in patients undergoing cardiac catheterization and possible percutaneous coronary intervention (PCI) was safe and can aid in identifying patients and artery segments at higher risk for subsequent non-culprit major adverse cardiovascular events (NC-MACE).

Despite advances in medical therapy and stenting, coronary artery disease remains the world's leading cause of death and causes extensive disability.¹ The ability to predict which patients or coronary segments will have future events has not been previously available; the LRP study successfully demonstrated the ability of IVUS+ NIRS imaging to prospectively detect vulnerable patients and vulnerable plaques.

The study titled, “*Identification of patients and plaques vulnerable to future coronary events with near-infrared spectroscopy intravascular ultrasound imaging: a prospective, cohort study,*” was first presented at the 2018 annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Diego, by Ron Waksman, M.D., of the MedStar Heart and Vascular Institute in Washington, D.C.

Waksman et al. concluded that, “NIRS-intravascular ultrasound imaging adds to the armamentarium as the first diagnostic tool able to detect vulnerable patients and plaques in clinical practice.”

In April 2019, due to the positive results from the LRP study data, the FDA expanded the indications for use of the Makoto™ Intravascular Imaging System to include the identification of patients and plaques at increased risk of MACE. Intravascular NIRS was developed, validated, and labeled for the detection of lipid core plaque (LCP).

The study authors called this the “first study to use the NIRS chemogram [a color-coded map that displays the presence of LCP in yellow and absence in red] to show predictive ability for future NC-MACE, both for the patient and plaque levels.” They added that IVUS+NIRS, “should be considered as a tool to guide patients and lesions at risk for unanticipated subsequent MACE.”

The LRP Study enrolled 1,563 patients at 44 medical centers across the U.S. and Europe, and utilized IVUS+NIRS technology to assess the lipid core burden index (LCBI) in stable and unstable patients requiring an angiogram procedure for new and ongoing cardiac symptoms.

The study met its co-primary endpoints: the association of patient-level maxLCBI_{4mm} with vulnerable patients, those who are likely to experience any non-culprit MACE, and the

¹ Benjamin EJ, Muntner P, Alonso A, et al. Heart disease and stroke statistics-2019 update: a report from the American Heart Association. *Circulation* 2019; 139: e56–528.

association of plaque-level maxLCBI_{4mm} with vulnerable plaques, untreated lesions within a pre-imaged segment likely to cause a future MACE in that specific segment. In evaluating vulnerable patients, the study found the occurrence of a non-culprit, or unstented, MACE event within 24 months is 18 percent higher with each 100 unit increase in maxLCBI_{4mm}. Moreover, a patient with a maxLCBI_{4mm} greater than 400 is at 89 percent higher risk than a patient with a lesser maxLCBI_{4mm}. In plaque-level analyses, risk of experiencing an event within a vulnerable coronary segment within 24 months is 45 percent higher with each 100 unit increase in maxLCBI_{4mm}; and, the likelihood of an event in a coronary segment with a maxLCBI_{4mm} greater than 400 is 322 percent higher than a segment with a lesser maxLCBI_{4mm}.

“This positive data further demonstrates the potential for IVUS+NIRS Imaging to be a tool to eventually predict future coronary events,” said Nozomu Fujita, President and CEO of Infraredx, a Nipro Company.

“This data will pave the way for how we diagnose, treat, and manage our high-risk coronary patients,” said Waksman. “This is a very important tool for the field of interventional cardiology, as we now have the ability to identify these patients that could be at risk for future events.”

“The use of imaging in the U.S. is underutilized,” said Gary S. Mintz, M.D., of the Cardiovascular Research Foundation and MedStar Cardiovascular Research Network. “With these new findings, we hope that this will bolster the conversation surrounding the use of imaging during PCI procedures and lead to the better diagnosis and treatment of our high-risk patient populations.”

Infraredx’s Makoto™ Intravascular Imaging System, with accompanying Dualpro™ IVUS+NIRS catheter, is the only technology on the market FDA-cleared for the identification of patients and plaques at an increased risk of MACE, and for the detection of LCP. The system utilizes NIRS to detect LCP and automatically displays the results via a simple, color-coded map, called a chemogram. The chemogram allows for the straightforward display of the presence of LCP in yellow and absence in red. The ability to detect LCP in order to stratify at-risk patients will enable cardiologists to make more personalized clinical decisions for their patients.

To learn more, visit: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)31794-5/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)31794-5/fulltext). For more information about the Makoto™ Imaging System or the LRP Study results, visit www.infraredx.com.

About Infraredx, a Nipro Company

Infraredx, Inc., a Nipro company, is advancing the diagnosis and management of coronary artery disease by providing cardiologists with the most precise imaging tools required to predict and ultimately prevent heart attacks. Infraredx is dedicated to advancing this important field of research and conducting landmark clinical trials to transform how we view and treat heart disease. Connect with Infraredx on [Twitter](#) and [LinkedIn](#).

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