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Head-to-Head Study Validates Consistent Performance of Microcatheter FFR

ACIST-FFR Study at EuroPCR 2017 Finds Strong Correlative Performance of Microcatheter Fractional Flow Reserve Measurement Compared to Standard Pressure Wires

PARIS and EDEN PRAIRIE, MINN. (May 17, 2017)— ACIST Medical Systems Inc., a Bracco Group Company, today announced results from the ACIST-FFR Study (Assessment of Catheter-based Interrogation and Standard Techniques for Fractional Flow Reserve measurement) demonstrating the consistent and correlative performance of the Navvus® MicroCatheter compared to standard pressure wire systems. ACIST-FFR is the largest, multi-center study to compare microcatheter FFR to pressure wire FFR, as well as the only study to include multiple pressure wire comparators. The study was presented for the first time at EuroPCR 2017, in Paris, France.

“As the use of FFR in clinical practice continues to grow, it becomes increasingly important to understand the benefits and limitations of each type of FFR technology in regards to delivering consistent measurements and making coronary intervention procedures as efficient as possible,” said ACIST-FFR co-principal investigator William F. Fearon, M.D., Stanford University School of Medicine, Stanford Cardiovascular Institute at Stanford University.

This prospective, multi-center study evaluated 245 patients with stable coronary artery disease at 11 U.S. centers, assessing the differences in fractional flow reserve values obtained using the Navvus MicroCatheter, to those using standard pressure wire systems. Patients’ FFR measurement was obtained by a pressure wire alone and with the microcatheter FFR over the pressure wire. All waveforms and measures were reviewed by an independent FFR core laboratory based upon pre-specified criteria for quality measurements.

Of the patients enrolled in the study, 169 had complete data meeting FFR core laboratory criteria. In these patients, an angiographic core lab used quantitative coronary angiography (QCA) to determine a mean reference vessel diameter (RVD) of 2.8mm, a mean lesion length of 15.3mm, and a mean diameter stenosis of 47 percent. Unique to this study, 30 percent of cases included a RVD <2.5 mm — prior microcatheter FFR clinical studies had only included vessels with RVD ≥2.5mm.

The FFR data showed that microcatheter FFR technology offered consistent and modestly lower FFR measurements when compared to a pressure wire, with an average difference of -0.022 (95% CI: -0.029, -0.015). In nearly all of the cases (97 percent), the differences in FFR measurements did not impact clinical decision-making.



“The difference found between FFR measurements with a pressure wire and microcatheter tended to be influenced by RVD and lesion length; however, from a practical perspective, the clinician can just look at the microcatheter FFR itself,” said ACIST-FFR co-principal investigator and presenter Matthew Price, M.D., director, Cardiac Catheterization Laboratory at Scripps Clinic. “The lower the Navvus FFR, the greater the bias. Since the bias is less at FFR values within the gray zone and higher, on average the clinical impact of the difference will be minimal.”

While the mean pressure drift was not different between the pressure wire and the microcatheter (0.015 vs. 0.015, $p=0.44$), the rate of clinically significant pressure drift was numerically higher with the pressure wire (7.4% vs. 3.5%, $p=0.10$).

“This study confirms and expands upon previous findings in a much more robust manner,” said Dr. Price. “It is encouraging to see these data further validate the diagnostic capabilities and technical merit of microcatheter FFR technology.”

Unlike standard pressure wires, the ACIST RXi® Rapid Exchange FFR System and Navvus® Rapid Exchange FFR MicroCatheter, allows physicians to use their 0.014” guide wire of choice throughout the procedure, addressing challenges of pressure wires, including accessibility in challenging anatomies, maintaining wire position, pressure-measurement drift and ease of obtaining post-intervention FFR.

“We are excited that the results of this direct comparison study add to the growing body of evidence supporting microcatheter FFR technology,” said Tom Morizio, President and CEO, ACIST Medical Systems, Inc. “This robust study and its findings reflect our commitment to proving out the technologies that simplify procedures and help physicians improve patient care.”

About FFR

FFR measurement is a technique used in cardiology to determine the effect of narrowing, or stenosis, in the coronary arteries on blood flow. It allows for a more effective assessment of coronary lesions than when only using angiography, the gold-standard imaging technique. By identifying which stenoses are causing ischemia by significantly restricting the blood flow to the heart muscle and causing the patient’s symptoms, FFR can help avoid unnecessary stenting to reopen the blood vessels, leading to improved patient outcomes.^{1,2}

About ACIST

ACIST Medical Systems, Inc. is a pioneering interventional and diagnostic technology company with a portfolio of advanced products, including the world’s first Rapid Exchange FFR and High Definition IVUS systems. It is also a global market leader in advanced contrast imaging systems for cardiovascular angiography and radiology imaging. Through these products, ACIST is demonstrating its commitment to bringing unique and innovative technologies that simplify cardiovascular procedures and empower clinicians to treat patients with superior care. As part of the Bracco Group, ACIST benefits from the resources of a multinational conglomerate with broad expertise in cath lab technology and a dedication to continuous advancement. Headquartered in Eden Prairie, Minnesota, USA, ACIST has



the power to

worldwide presence with over 300 direct employees and facilities in Silicon Valley, Heerlen, and Tokyo. To learn more about ACIST, visit www.acist.com.

Bracco Group

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¹ Tonino PA et al. New Engl J Med 2009;360:213-24

² De Bruyne B et al. New Engl J Med 2012;367:991-1001