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Impact of Post-Intervention Fractional Flow Reserve Measurement on Acute PCI Outcomes Investigated in Large Independent Registry

FFR-Search Late-Breaking Registry Finds Nearly Half of Patients Have FFR Lower than 0.90 After PCI

Future Two Year Follow-up of the Low FFR Measurements' Impact on Clinical Outcomes Will Have Important Clinical Considerations for Interventional Cardiology

PARIS and EDEN PRAIRIE, MINN. (May 18, 2017)— Revealing a potential new role for fractional flow reserve (FFR) in cath labs, investigators from the Erasmus Medical Center unveiled early results from the independent, physician-sponsored FFR-Search Registry, which revealed an association between post-percutaneous coronary intervention (PCI) FFR measurements with the ACIST Navvus® Rapid Exchange FFR MicroCatheter and clinical outcomes. The investigators found that microcatheter-based FFR was feasible in various clinical settings, including acute coronary syndromes and ST elevation myocardial infarction, and almost half of patients had an FFR lower than 0.90 after PCI. As anticipated, these early results did not have a meaningful impact on 30-day clinical outcomes; patients will now be followed out to the two-year primary endpoint to shed more definitive light on the value of post-PCI FFR in clinical practice. These early findings were presented during a late-breaking trial session at EuroPCR 2017 in Paris, France.

The registry enrolled over 1,000 consecutive patients with stable angina or acute coronary syndromes that had undergone percutaneous coronary intervention at Erasmus Medical Center in Rotterdam to determine the association of post-PCI FFR values on clinical outcomes, as measured at 30-days, one-year, two-years and five-years follow-up. In an attempt to replicate real world clinical practice, the protocol precluded operators from additional optimization techniques after the initial stent placement.

Using the ACIST Navvus Rapid Exchange FFR MicroCatheter — an ultra-thin monorail microcatheter with fiber-optic technology — the average post-PCI FFR value was 0.96 in a resting state and 0.91 under hyperemic conditions in the 959 patients who were able to undergo FFR measurement. Utilizing the microcatheter technology allowed the investigators the unique benefit of delivering the pressure sensor diagnostic directly over any 0.014" workhorse guidewire post-PCI and only added approximately 5 minutes to the overall procedural time. Interestingly, 22 percent of patients whose lesions were stented still had at least one post-PCI FFR measurement less than or equal to 0.85. The primary clinical endpoint is MACE defined as all-cause mortality, myocardial infarction (MI) and any revascularization.

The initial 30-day data found that FFR measurements greater than 0.9 resulted in a MACE rate of 1.5 percent, while measurements less than 0.9 resulted in a MACE rate of 2.3 percent (p=ns). Furthermore, as the FFR measurements decreased in patients, the MACE rates numerically increased. While the patient cohorts with FFR measurements below 0.90 were underpowered to show statistical differences between groups, FFR measurements in the 0.86-0.90, 0.81-0.85 and less than or equal to 0.80 ranges resulted in MACE rates of 2.0 percent, 2.6 percent, and 2.8 percent, respectively.

“As FFR becomes more and more the standard to determine treatment approaches in patients with coronary artery disease, we are excited to see that this technology is safe, fast and easy to apply — as well as may be used to optimize longer-term outcomes after interventional procedures,” said FFR-Search investigator Dr. Nicolas M. Van Mieghem, MD, PhD, FESC, co-principal investigator and Director of Interventional Cardiology at Thoraxcenter, Erasmus Medical Center in Rotterdam, Netherlands. “The preliminary data from FFR-Search has the potential to significantly expand this technology’s role in the cath lab in the future, which is why we’re eager to see the important results of the primary endpoint at two years.”

In 60 of the patients having an FFR value equal to or less than 0.85, an intravascular high definition ultrasound analysis was performed to identify potential causes for the low post procedural FFR measurement. Stent under-expansion was the most frequently identified cause for low FFR, found in 84 percent of the cases, followed by focal lesions distal to the stent (52 percent), focal lesions proximal to the stent (43 percent) and stent malapposition (22 percent).

“Based on these results, we look forward to continuing to build the evidence supporting this new role of FFR,” said FFR-Search co-investigator and presenter Dr. Roberto Diletti, MD, Interventional Cardiology at Thoraxcenter, Erasmus Medical Center in Rotterdam, Netherlands. “We are eager to see how the outcomes will unfold at one, two and five years, and how we may be able to best optimize these findings through further intervention after the post-treatment FFR measurement.”

Unlike traditional pressure wires, the ACIST RXi® Rapid Exchange FFR System and Navvus® Rapid Exchange FFR MicroCatheter, allows physicians to use their 0.014” guidewire 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.

“Given that our differentiated microcatheter technology allows physicians the ability to perform rapid FFR measurements before, during and after intervention, all while maintaining their guidewire position, we feel that we are uniquely suited to address this new role of FFR compared to other FFR measurement modalities, including pressure wire-based FFR,” said Tom Morizio, President and CEO, ACIST Medical Systems, Inc. “We look forward to partnering with physicians to develop this new approach and are optimistic about the possibility of our technology playing a new role in improving outcomes.”

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 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