ALL-RISE: Angiography-Derived Physiology Non-Inferior to Pressure Wire for PCI

Written by The Life Science Feed Editorial Team · Published 19 May 2026 · Edited by William Lopes

Guidance for percutaneous coronary intervention (PCI) has traditionally relied on invasive pressure wire measurements to assess lesion significance. However, the ALL-RISE trial, presented at ACC.26, indicates that angiography-derived coronary physiology offers a non-inferior alternative, potentially simplifying PCI procedures without compromising patient outcomes.

KEY TAKEAWAYS

- The Pivot: Angiography-derived coronary physiology can guide PCI as effectively as invasive pressure wire measurements.
- The Data: The primary composite endpoint occurred in 6.2% of the angiography-derived group versus 6.5% in the pressure wire group (HR 0.95, 95% CI 0.80-1.13, p for non-inferiority The Action: Clinicians may consider angiography-derived physiology as a viable, less invasive option for PCI guidance, particularly in settings where pressure wire access or expertise is limited.

The assessment of coronary lesion severity prior to percutaneous coronary intervention (PCI) is critical for optimizing revascularization strategies and improving patient outcomes. Historically, invasive pressure wire-based techniques, such as fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR), have been the gold standard for physiological lesion assessment. These methods provide precise, real-time data on blood flow dynamics across a stenosis, guiding decisions on whether to intervene.1 However, pressure wire procedures add complexity, cost, and time to the catheterization laboratory, and require specialized equipment and expertise.2 The development of angiography-derived physiological assessment methods, which utilize standard angiographic images to calculate functional lesion significance, offers a potentially less invasive and more accessible alternative. The clinical dilemma has been whether these non-invasive methods can provide comparable safety and efficacy to the established invasive techniques. The global burden of coronary artery disease (CAD) necessitates efficient and effective diagnostic tools, as CAD remains a leading cause of morbidity and mortality worldwide. Given the high volume of PCI procedures performed annually, even marginal improvements in efficiency and accessibility can have substantial public health implications.

The ALL-RISE Trial

The ALL-RISE trial was a large-scale, global, randomized controlled trial designed to evaluate the non-inferiority of angiography-derived coronary physiology compared with an invasive pressure wire-based approach to guide PCI. The trial enrolled 5,000 patients with stable angina or acute coronary syndromes requiring PCI across 150 centers worldwide.3 Patients were randomized 1:1 to either angiography-derived physiology guidance or conventional pressure wire guidance. The primary endpoint was a composite of all-cause death, myocardial infarction (MI), or unplanned

revascularization at one year. Secondary endpoints included procedural time, contrast volume, and cost-effectiveness.3 The inclusion criteria focused on patients with at least one coronary artery stenosis amenable to PCI, with specific exclusion criteria for conditions that might confound physiological assessment, such as severe valvular heart disease or cardiogenic shock. This ensured a relatively homogenous patient population suitable for direct comparison of the two assessment strategies.

In the angiography-derived physiology arm, lesion assessment was performed using proprietary software that analyzes standard angiographic images to calculate a functional severity index. This software typically employs computational fluid dynamics or machine learning algorithms to simulate blood flow and pressure gradients across the stenosis based on the vessel geometry derived from the angiogram. PCI was then performed based on these calculations. In the pressure wire arm, FFR or iFR measurements were obtained using a guidewire, and PCI decisions were made according to established guidelines for physiological revascularization. All operators were trained in both techniques, and core lab adjudication was used for all angiographic and clinical events to ensure blinding and consistency.4 Standardized protocols for both angiography acquisition and pressure wire measurements were strictly adhered to across all participating centers to minimize variability.

The trial demonstrated that angiography-derived coronary physiology was non-inferior to the invasive pressure wire-based approach for guiding PCI. The primary composite endpoint of all-cause death, MI, or unplanned revascularization at one year occurred in 6.2% of patients in the angiography-derived group compared to 6.5% in the pressure wire group (Hazard Ratio (HR) 0.95, 95% Confidence Interval (CI) 0.80-1.13, p for non-inferiority).5 This met the pre-specified non-inferiority margin. There were no statistically significant differences in the individual components of the primary endpoint between the two groups. Procedural time was significantly shorter in the angiography-derived group (mean difference -8.5 minutes, P -15 mL, P 5 These findings suggest that angiography-derived methods can streamline the PCI procedure while maintaining comparable safety and efficacy. The trial also reported a trend towards reduced procedural costs in the angiography-derived arm, although this was a secondary endpoint and requires further economic analysis.6 The reduction in procedural time and contrast volume offers tangible benefits, potentially reducing patient exposure to radiation and nephrotoxic agents, and improving cath lab efficiency.

While the ALL-RISE trial provides compelling evidence for the non-inferiority of angiography-derived physiology, certain limitations warrant consideration. The trial population predominantly included patients with less complex coronary artery disease. The generalizability to patients with highly calcified lesions, chronic total occlusions, or diffuse disease may require further investigation. These complex anatomies can pose challenges for accurate angiographic assessment due to foreshortening, vessel overlap, or poor image quality, potentially impacting the reliability of angiography-derived calculations. Additionally, the proprietary nature of the angiography-derived software means that its widespread adoption is dependent on commercial availability and integration into existing cath lab workflows. Future research should focus on real-world implementation, cost-effectiveness in diverse healthcare systems, and long-term outcomes beyond one year. Further sub-analyses exploring specific lesion characteristics and operator experience with the angiography-derived tools would also be beneficial. The learning curve associated with new software platforms and the need for robust validation across different imaging systems are also important considerations for broader clinical application.

CLINICAL IMPLICATIONS

The ALL-RISE trial results present a significant shift in the landscape of PCI guidance. For clinicians, the ability to achieve non-inferior outcomes using angiography-derived physiology means a less invasive, potentially faster, and more cost-effective approach to lesion assessment. This could be particularly impactful in centers where pressure wire equipment is not readily available or where operators have less experience with its use. The reduction in procedural time and contrast volume is a tangible benefit, especially for patients with renal impairment or those undergoing complex multi-vessel PCI. It also frees up valuable cath lab time, potentially increasing throughput.

From a patient perspective, avoiding the additional step of inserting a pressure wire could translate to a marginally reduced risk of procedural complications, though these are already low. More broadly, the simplification of the procedure might make physiological assessment more accessible, ensuring that more patients receive evidence-based revascularization decisions rather than purely anatomical ones. This democratizes access to advanced physiological guidance, moving it beyond highly specialized centers. However, patients and referring GPs should be aware that while non-inferior, the technology is still relatively new and its long-term performance in all clinical scenarios will continue to be monitored.

For the medical device industry, this trial validates the investment in angiography-derived physiology platforms. Companies developing these technologies, such as those offering QFR or vFFR, will likely see increased adoption and market penetration. This could lead to a competitive environment driving further innovation and potentially reducing the cost of these systems over time. Guideline bodies like the ESC and ACC will need to review these data and consider updating their recommendations to incorporate angiography-derived physiology as a class I or IIa recommendation, alongside traditional pressure wire methods. The challenge will be ensuring adequate training and quality control for these new tools to maintain the high standards of PCI outcomes.

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