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THE PRESENT AND FUTURE

TECHNOLOGY CORNER

Standardization of Fractional Flow Reserve Measurements

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CME Objective for This Article: After reading this article, the reader should be able to: 1) perform fractional flow reserve measurement in an accurate, standardized manner; 2) recognize and avoid potential pitfalls of fractional flow reserve measurement; and 3) conduct clinical studies that involve fractional flow reserve in a standardized and thus reproducible/comparable manner.

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Standardization of Fractional Flow Reserve Measurements

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ABSTRACT

Pressure wire–based fractional flow reserve is considered the standard of reference for evaluation of the ischemic potential of coronary stenoses and the expected benefit from revascularization. Accordingly, its application in daily practice or for research purposes has to be as standardized as possible to avoid technical or operator-related artifacts in pressure recordings. This document proposes a standardized way of acquiring, recording, interpreting, and archiving the pressure tracings for daily practice and for the purpose of clinical research involving a core laboratory. Proposed standardized steps enhance the uniformity of clinical practices and data interpretation. (J Am Coll Cardiol 2016;68:742–53)

To assess the contribution of a new diagnostic test, a hierarchical model of efficacy was proposed by Fryback and Thornbury (1). Although the model was developed for the evaluation of diagnostic imaging, its parameters also apply to "physiological imaging," with its attributes of: 1) technical quality; 2) diagnostic accuracy; 3) diagnostic thinking efficacy; 4) effect on therapy; 5) patient's outcome; and 6) economic aspects (**Central Illustration**). A key feature of this model is that for a test to be efficacious at a higher level in this hierarchy, it must be efficacious at lower levels.

Since the first description of pressure wire-based fractional flow reserve (FFR) (2–4), an abundance of data pertaining to each of these criteria have been reported. Accordingly, FFR is now considered to be the reference standard for the evaluation of the ischemic potential and the expected benefit from revascularization of coronary stenosis (5–8). Moreover, FFR is increasingly being used in clinical trials as an inclusion criterion or as an endpoint (9) and to validate new diagnostic modalities (10,11). Although all major outcomes-randomized clinical trials have made decisions on the basis of operator-derived FFR values, a handful of recent diagnostic accuracy studies sent tracings to physiology core laboratories for post hoc analysis. However, no matter where analysis takes place, technical or operator-related artifacts in pressure recordings should be avoided, minimized, or at least identified if they occur.

FFR is calculated from distal coronary pressure (P_d) and aortic pressure (P_a) obtained during maximal coronary hyperemia. In principle, these measurements are straightforward and almost fully automated, as illustrated in **Figure 1**. Yet, minor differences among practices of different laboratories have led to some heterogeneity in acquiring and interpreting the data. Because FFR-based decisions are important for patients' outcomes, and given the need for rigor and reproducibility in reading the tracings by core laboratories, the highest technical quality of FFR measurements is desirable. As FFR by itself is a highly reproducible diagnostic measure, deviations mainly derive from a lack of standardization (12).

Accordingly, this document proposes a standardized way of acquiring, recording, interpreting, and

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