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Intervention

Performance and 12-month Outcomes of a Wire-free Fractional Flow Reserve System for Assessment of Coronary Artery Disease

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Abstract

Background: Fractional flow reserve (FFR) using an invasive pressure wire is recommended to guide coronary revascularisation in stable coronary artery disease. Coronary angiography-based wire-free FFR (CAFFR) determines the significance of a coronary lesion without the requirement of a pressure wire. Deferral of revascularisation of coronary lesions with an FFR >0.8 has been shown to have similar outcomes to patients managed with optimal medical therapy. **Objective:** The aim of our study was to assess the performance and 12-month clinical outcomes in patients with CAFFR-guided percutaneous coronary intervention (PCI) deferral. **Methods:** This was a prospective study involving 69 patients (93 vessels) with angiographic stenosis of 30–90%. Patients with CAFFR ≤0.80 or poor image quality were excluded, leaving 29 patients (31 vessels) for analysis. All recruited patients had a CAFFR >0.80 and thus, PCI deferral. This cohort was followed up for 12 months. The primary endpoint was a composite of death from any cause, MI or target vessel revascularisation. Wired FFR was done for comparison on 14 patients (48%) at the operator's discretion. **Results:** The mean age was 59.9 (±12.6) years. The majority of patients were men (83%; n=24), 41% (n=12) had diabetes, 62% (n=18) had hypertension, 59% (n=17) had dyslipidaemia, 62% (n=18) had a history of smoking. The mean left ventricular ejection fraction (LVEF) was 52 (±11.4)% and 76% of the patients had a recent acute coronary syndrome. We assessed the left anterior descending artery and 52% (n=16) of vessels had a mean CAFFR was 0.87. At 12 months, all patients were alive, 89.7% remained in chronic coronary syndrome (CCS) class 1 and 3.4% (n=1) of the study population met the primary outcome of target vessel revascularisation. **Conclusion:** CAFFR showed good agreement with wire-based FFR and 12-month outcomes showed that CAFFR-guided deferral of PCI was safe and comparable to wired-based FFR guidance.

Keywords

Coronary artery disease, fractional flow reserve, wire-free fractional flow reserve, Malaysia

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Informed consent/consent to publish: No informed consent was required for this study as it received an ethics waiver from the Malaysian research and ethics committee.

Data Availability Statement: Data is available on request from the corresponding author due to privacy/ethical reasons.

Ethical approval: This study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Trial registration number: NMRR-07-20-250

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Fractional flow reserve (FFR) using an invasive pressure wire has a Class 1A recommendation for guiding coronary revascularisation in stable coronary artery disease (CAD).[1] A pressure wire-based index is used during coronary angiography to assess the potential of a coronary stenosis to induce myocardial ischaemia.[2–5] There is robust data for deferring percutaneous coronary intervention (PCI) in lesions deemed not significant by FFR versus angiography alone.[5–11] FFR is determined by inducing maximum hyperaemia with medications such as IV or intra-coronary adenosine. Deferral of PCI guided by wire-based FFR has also shown favourable long-term outcomes in studies such as FAME.[8] When FFR is used to guide PCI, clinical outcomes are improved with fewer stents being deployed.[8,12] Unfortunately, FFR remains underused in diagnostic and PCI procedures. A report from the CathPCI Registry of the National Cardiovascular Data Registry from 2011 (data collected from Jan