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3-year outcomes in stable coronary artery disease patients with diabetes based on a novel index: computational pressure-flow dynamics derived fractional flow reserve

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Introduction

Computational pressure-flow dynamics derived fractional flow reserve (caFFR) has been developed for determining fractional flow reserve (FFR) in stable coronary artery disease (CAD) patients, without hyperaemic induction and invasive guidewire placement in traditional FFR.

Despite previous validation on the diagnostic accuracy of caFFR, it was unclear whether its clinical value in diabetic patients, who are at risk of coronary microvascular dysfunction, would decline. The aim of the study is to evaluate the clinical value of caFFR in stable CAD patients with diabetes.

Wire-based FFR	caFFR
Invasive • Measured by inserting a guiding catheter and pressure-sensing wire to derive the ratio of mean distal coronary pressure to mean aortic pressure • Intravenous adenosine is used as hyperaemic stimulus.	Non-invasive • Avoid the need of invasive pressure wire and hyperaemic stimulus • Eliminate wire-related complications and chest discomfort caused by hyperaemia.
Utilization • Low utilization rate despite being Class 1 indication according to European Society of Cardiology (ESC)[1]	Utilization • Derived using angiograms and computational fluid-dynamic method • Could be performed within 3 minutes • Diagnostic accuracy has been validated to be 96%. [2] • caFFR and wire-based FFR showed a strong correlation. (R=0.803) • Its non-invasive nature and high efficiency could potentially increase its utilization
In multivessel CAD patients • Not convenient for multivessel CAD patients as the invasive procedure has to be performed in every stenosed vessel.	In multivessel CAD patients • Can access multivessel disease more quickly using angiograms

Results

Among the diabetic cohort, there were 111 adherent patients and 101 non-adherent patients. PCI was performed in 62.3% of them. A total of 26 composite events occurred, including 5 cardiovascular death, 5 non-fatal MI, 2 strokes and 14 subsequent revascularizations. Adherent patients had significantly lower incidence of MACE than non-adherent patients (5.4% vs 15.8%; P=0.01). Following multivariate adjustment, adherent patients had a significantly lower risk of MACE than non-adherent patients (adjusted hazard ratio [HR], 0.33; 95% confidence interval [CI], 0.13-0.83; P=0.02).

Similarly, adherence to caFFR significantly reduces the risk of MACE in non-diabetic patients (adjusted HR, 0.49; 95%CI, 0.32-0.74; P<0.01). The risk of MACE was similar between adherent groups in diabetic and non-diabetic population (adjusted HR, 1.21; 95%CI, 0.50-2.96; P=0.67).

Methodology

We studied 1253 stable CAD patients (mean age=66.3±10.8, male 72.9%), including 212 diabetic patients and 1041 non-diabetic patients.

According to the FFR threshold of 0.8, patients were said to be adherent if all vessels with caFFR≤0.8 were treated with percutaneous coronary intervention (PCI) and all vessels with caFFR>0.8 were not. Otherwise, they were said to be non-adherent. The primary endpoint was 3-year major adverse cardiac events (MACE), defined as a composite of cardiovascular death, non-fatal myocardial infarction (MI), stroke and subsequent revascularization.

Conclusion

In stable CAD patients with and without diabetes, treatment adherence to caFFR significantly reduces the risk of MACE at 3 years. This was the first outcome study supporting the potential clinical use of caFFR in guiding revascularization decisions in diabetic patients.

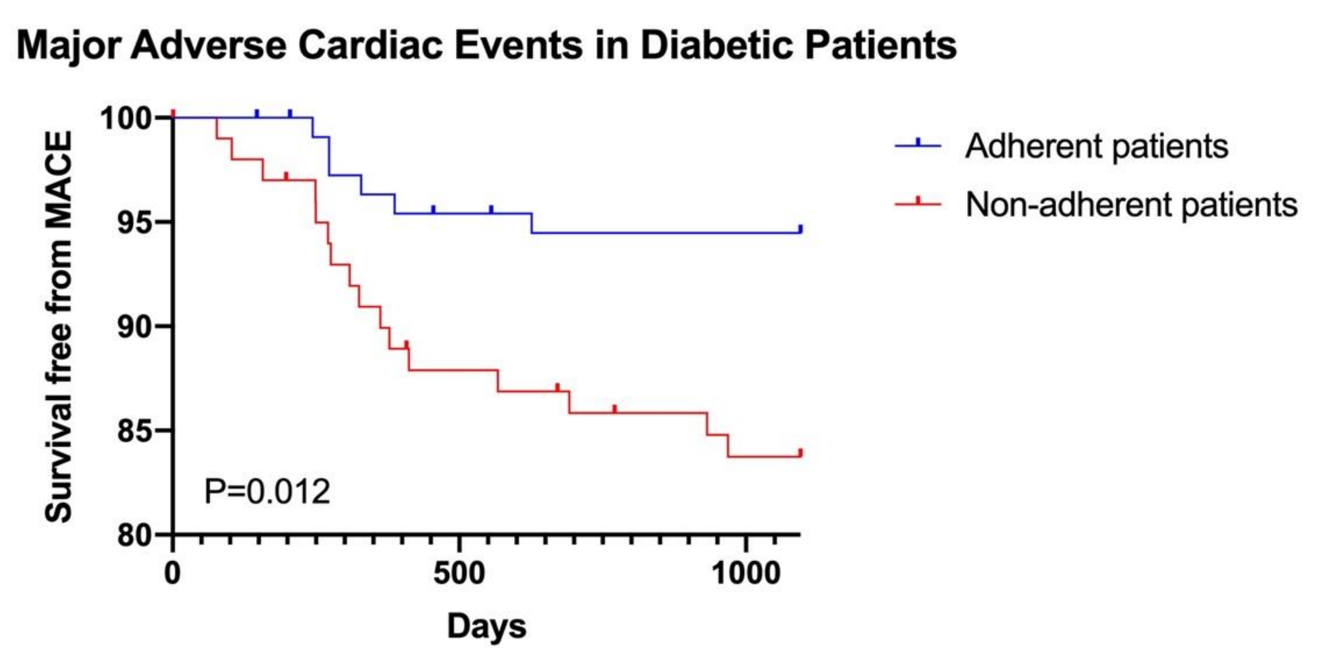

Figure 1a. Kaplan-Meier survival curves for MACE in diabetic patients

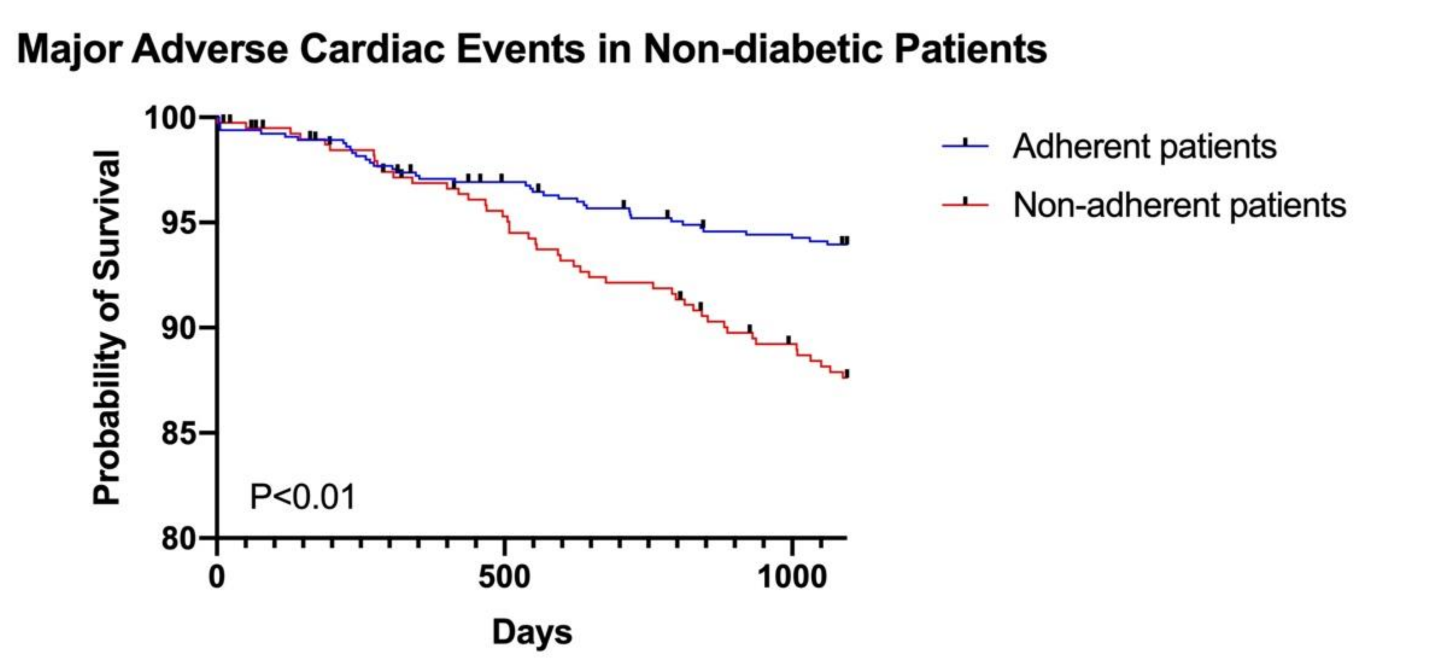

Figure 1b. Kaplan-Meier survival curves for MACE in non-diabetic patients

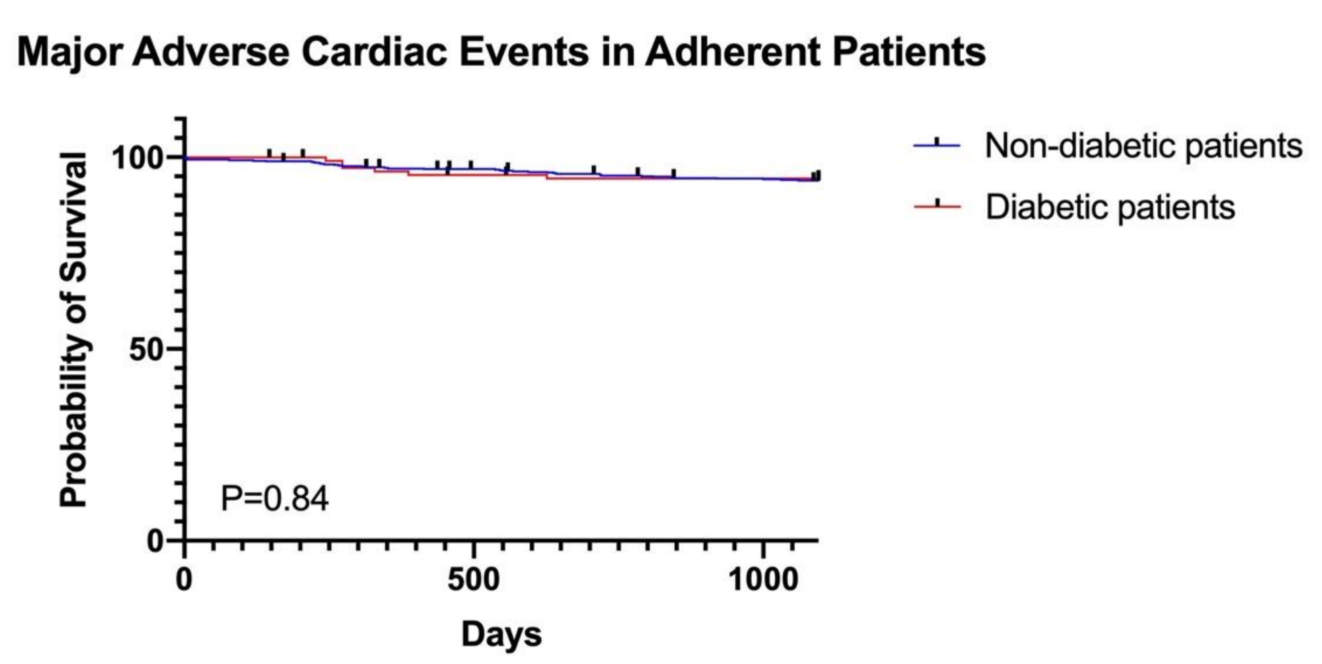

Figure 1c. Kapan-Meier survival curves for MACE between adherent groups in diabetic and non-diabetic patients

1. European Heart Journal, Volume 40, Issue 2, 07 January 2019, Pages 87–165, https://doi.org/10.1093/eurheartj/ehy394
2. Li, Jianping, Gong, Yanjun, Wang, Weimin, Yang, Qing, Liu, Bin, Lu, Yuan, Xu, Yawei, Huo, Yunlong, Yi, Tieci, Liu, Jian, Li, Yongle, Xu, Shaopeng, Zhao, Lei, Ali, Ziad A, and Huo, Yong. "Accuracy of Computational Pressure-fluid Dynamics Applied to Coronary Angiography to Derive Fractional Flow Reserve: FLASH FFR." *Cardiovascular Research* 116.7 (2020): 1349-356. Web.

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