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Review of Imaging and Physiology Late Breaking Trials From the TCT Connect 2020 Virtual Meeting

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1. Introduction

Virtual meetings continue to replace in-person meetings across the world amidst the coronavirus disease 2019 (COVID-19) pandemic. Despite this, highly anticipated clinical research continues to be presented, with broader audiences no longer limited by distance or cost. In this article, we present a brief overview of the imaging and physiology late-breaking clinical trials presented at the Transcatheter Cardiovascular Therapeutics (TCT) Connect 2020 virtual conference that carry significant clinical implications.

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2. Imaging

2.1. PROSPECT II: A prospective natural history study using NIRS-IVUS imaging in patients with acute myocardial infarction

Presenter: Dr. David Erlinge

Key Points: An analysis of new data from the prospective PROSPECT II natural history study of myocardial infarction (MI) patients post-percutaneous coronary intervention (PCI) suggests that near-infrared spectroscopy (NIRS) – intravascular ultrasound (IVUS) intracoronary imaging could help flag high-risk vulnerable plaques.

The findings were presented by David Erlinge, MD, of Skane University Hospital, Sweden [1]. Despite improved MI treatment options, ischemic heart disease is one of the leading causes of death globally, with acute coronary syndromes (ACS) often arising from the rupture and thrombosis of lipid-rich atherosclerotic plaques. Identifying lesions that, though currently non-obstructive, could pose future risk may enable pre-emptive strategies to stabilize the plaque and improve outcomes.

The PROSPECT II trial followed 898 MI patients (83% men) with a mean age of 62.7 years (varying by 10 years) for a median of 3.7 years

Abbreviations

ACS	acute coronary syndrome
AMI	acute myocardial infarction
CAD	coronary artery disease
CFR	coronary flow reserve
CI	confidence interval
COVID-19	coronavirus disease 2019
CSA	cross-sectional area
CTCA	computed tomography coronary angiography
DES	drug-eluting stent
FFR	fractional flow reserve
FFR-CT	fractional flow reserve computed tomography
HR	hazard ratio
HTA	health technology assessment
ICA	invasive coronary angiography
iFR	instantaneous wave-free ratio
IVUS	intravascular ultrasound
MACCE	major adverse cardiac or cerebrovascular events
MACE	major adverse cardiovascular events
maxLCBI _{4mm}	maximum Lipid Core Burden Index over a 4-mm length
MI	myocardial infarction
MLA	minimal lumen area
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIRS	near-infrared spectroscopy
NSTEMI	non-ST-segment elevation myocardial infarction
OCT	optical coherence tomography
OR	odds ratio
PCI	percutaneous coronary intervention
PIOS	physiology-guided incremental optimization strategy
SAQ-AF	Seattle Angina Questionnaire Angina Frequency
STEMI	ST-elevation myocardial infarction
TCFA	thin cap fibroatheroma
TCT	Transcatheter Cardiovascular Therapeutics
TLR	target lesion revascularization
TVMI	target vessel myocardial infarction
TVF	target vessel failure

between 2014 and 2017 following successful PCI. Patients with troponin-positive MI (ST-elevation myocardial infarction [STEMI] > 12 h or non-ST-elevation myocardial infarction [NSTEMI]) were prospectively enrolled across Sweden, Denmark, and Norway, with combination NIRS-IVUS intravascular catheter imaging performed after successful PCI of all culprit lesions in the proximal 6 to 8 cm of all three coronary arteries. A total of 3629 untreated non-culprit lesions were characterized using NIRS-IVUS, IVUS for plaque burden and minimal lumen area (MLA), and NIRS for lipid level.

The primary and major secondary endpoints were the covariate-adjusted relationship between lipid-rich plaques, defined as those with the highest quartile of the NIRS-defined maximum Lipid Core Burden Index over a 4-mm length (maxLCBI_{4mm}) and patient-level and lesion-level major adverse cardiovascular events (MACE), respectively. The researchers also assessed the maxLCBI_{4mm} cutoff of 400 or more as a secondary sensitivity analysis. IVUS-defined parameters of plaque burden of 70% or more and MLA of 4 mm² or less were also assessed to identify high-risk vulnerable plaque. Subsequent MACE, either requiring revascularization or with rapid lesion progression, were then monitored on the basis of follow-up angiography arising from either originally treated culprit or untreated non-culprit lesions.

The researchers found that adverse events within 4 years occurred in 13.2% of patients, with the highest percentage of events (8%) arising from untreated non-culprit lesions with a mean baseline diameter

stenosis of 46.9%. PROSPECT II showed that patients with a high plaque burden had a threefold increase in patient-level risk (odds ratio [OR], 3.09; 95% confidence interval [CI]: 1.65, 5.76), and an 11-fold increase in lesion-level risk (OR, 11.37; 95% CI: 5.60, 23.11). Those with high-lipid plaques had patient risk doubled from 4.8% to 10.1%, and on the lesion level a sevenfold increase, from 0.5% to 3.8%.

NIRS-IVUS-identified plaques with both high lipid content and high plaque burden had a substantially higher risk, with 7% MACE risk at the lesion level. Furthermore, the investigators found that having neither high plaque burden nor high lipid level in a plaque resulted in a very low risk of events (0.2%). During the presentation, Erlinge said the findings should at least prompt treatment of patients found to have these kinds of “high-risk” plaques with lipid-lowering therapy and implement a preventative strategy. He and fellow researchers now call for further studies prospectively using this information to improve outcomes for high-risk patients with coronary artery disease (CAD).

The study received funding from Abbott Medical Devices, InfraRedX, and The Medicines Company.

2.2. COMBINE (OCT-FFR): A prospective natural history study using OCT imaging in patients with diabetes

Presenter: Dr. Elvin Kedhi

Key Points: A prospective study shows that diabetic patients with negative fractional flow reserve (FFR) (>0.80) and high-risk features on optical coherence tomography (OCT)-thin cap fibroatheroma (TCFA) have higher adverse events during follow-up.

FFR is used to guide the revascularization strategy in patients with intermediate lesions. The conventional approach is that FFR-negative lesions (>0.80) are treated medically and FFR-positive lesions (≤0.80) are treated with revascularization. Elvin Kedhi, MD, PhD, of Liberal Universiteit Brussel, Belgium, presented the results of the COMBINE study [2].

In the COMBINE (OCT-FFR) study, diabetic patients undergoing angiography with at least one non-culprit lesion with stenosis of 40% to 80% and FFR >0.80 underwent OCT and were assigned to a group based on TCFA identified on OCT. The primary endpoint was target lesion-related MACE, defined as cardiac death, target vessel myocardial infarction (TVMI), clinically driven target lesion revascularization (TLR), or hospitalization due to unstable or progressive angina at 18 months.

A total of 550 patients were enrolled, 547 entered the study procedure, 423 had an FFR >0.80, and 112 had an FFR ≤0.80. Out of 423 patients who had an FFR >0.80, 390 had OCT. In 292 patients, there was no evidence of TCFA, and 98 patients had TCFA. At 18 months, the primary endpoint was significantly higher in the group with TCFA (13.3% vs. 3.1%; hazard ratio [HR], 4.7; 95% CI: 2.0, 10.9; p=0.0004). Results of the primary endpoint were driven by significantly higher rates of TVMI, TLR, and hospitalization for unstable or progressive angina. On multivariable Cox regression analysis, TCFA and minimal lumen area decrease of 1 mm² were noted to be significant predictors of adverse events.

Kedhi concluded that in diabetic patients, more than 25% of all FFR-negative lesions have high-risk features on OCT (TCFA), and these patients have a significantly higher risk of target lesion-related adverse events at 18 months. Kedhi suggested that combined FFR and OCT can improve the lesion assessment in these high-risk patients and should be the preferred approach.

This study was funded by a research grant from St. Jude Medical (Abbott).

2.3. ULTIMATE: Three-year outcomes after IVUS-guided vs angiography-guided DES implantation

Presenter: Dr. Jun-Jie Zhang

Key Points: At 3 years, IVUS guidance for complex coronary lesions undergoing drug-eluting stent (DES) implantation continued to show a

significantly lower target vessel failure (TVF) rate than DES implantation with angiography guidance alone.

Jun-jie Zhang, MD, PhD, of Nanjing First Hospital, China, presented the 3-year results of the ULTIMATE trial, which showed a sustained advantage for IVUS that was first reported with the 1-year results, which Zhang presented at TCT 2018 [3]. The 3-year study results were also simultaneously published online in *JACC: Cardiovascular Interventions* [4].

The ULTIMATE trial enrolled 1448 all-comers with *de novo* lesions between August 2014 and May 2017 in 8 Chinese centers. The patients were randomized 1-to-1 to undergo IVUS or angiography guidance. IVUS-defined criteria for optimal stent deployment were the following: minimal lumen cross-sectional area (CSA) $>5.0 \text{ mm}^2$ in the stented segment or 90% of the distal reference CSA; plaque burden $<50\%$ at 5 mm proximal or distal to the stent edge; and no edge dissection involving media with length $>3 \text{ mm}$.

At baseline, there were no differences between the two groups, with mean age 65.2 years in the IVUS group and 65.9 years in the angiography group, 73.9% of IVUS patients were men compared with 73.2% of angiography patients, and there were similar rates in both groups of hypertension, diabetes, current smoking, unstable angina, and acute myocardial infarction (AMI). At 1 year, the TVF rate was much lower in the IVUS group (2.9% vs. 5.4%; HR, 0.53; 95% CI: 0.31, 0.90; $p=0.02$). This advantage was sustained at 3 years (6.6% vs. 10.7%; HR, 0.60; 95% CI: 0.42, 0.87; $p=0.01$), largely driven by clinically driven target vessel revascularization (4.5% vs. 6.9%; HR, 0.64; 95% CI: 0.41, 1.00; $p=0.05$). Finally, a comparison of optimal vs. suboptimal PCI showed a significantly lower TVF rate in patients who underwent optimal PCI (4.2% vs. 9.2%; HR, 0.44; 95% CI: 0.24, 0.81).

The ULTIMATE trial was funded by the National Natural Science Foundation of China.

3. Physiology

3.1. DEFINE-PCI: One-year outcomes in patients with post-PCI residual ischemia

Presenter: Dr. Manesh Patel

Key Points: While an instantaneous wave-free ratio (iFR) cutoff of ≤ 0.89 can tell clinicians when to revascularize, a different cutoff, ≥ 0.95 , might show clinicians how to optimally revascularize.

Manesh Patel, MD, of Duke Clinical Research Institute, presented the 1-year follow-up results of the DEFINE-PCI study [5]. The objectives were to assess the change in the Seattle Angina Questionnaire Angina Frequency (SAQ-AF) score, assess clinical events and perform a *post hoc* analysis to determine whether a post-PCI iFR value is associated with improved outcomes.

The top-line DEFINE-PCI results were reported at the American College of Cardiology (ACC) Scientific Sessions 2019. The prospective, observational study evaluated blinded iFR pullback in 500 patients who underwent PCI. The primary endpoint was the rate of residual ischemia, defined as iFR <0.90 , after angiographically successful PCI; 24% of patients met this definition, and 81.6% of this was attributable to angiographically inapparent focal lesions. The baseline SAQ-AF score was 73.3 ± 22.8 , and it rose by at least 10 points at 12 months in 63.1% of patients with a post-PCI iFR <0.90 as compared with 71% of patients with a post-PCI iFR ≥ 0.90 , a difference that did not reach statistical significance ($p=0.17$). In the most symptomatic patients (baseline SAQ-AF ≤ 60), SAQ-AF rose by at least 10 points more frequently in patients with a post-PCI iFR ≥ 0.95 compared with those with a post-PCI iFR <0.95 (100.0% vs. 88.5%; $p=0.01$).

Furthermore, patients with post-PCI iFR ≥ 0.95 had a significantly lower composite clinical event rate (cardiac death, spontaneous MI, or clinically driven target vessel revascularization) at 1 year than patients with post-PCI iFR <0.95 (1.8% vs. 5.7%; HR, 3.38; 95% CI: 0.99, 11.6; log-rank $p=0.04$). This was also true

when examining only the composite of cardiac death or spontaneous myocardial infarction (0.0% vs. 3.2%; log-rank $p=0.02$). The clinical effectiveness of post-PCI iFR ≥ 0.95 to identify and eliminate post-PCI ischemia will be studied in the prospective randomized DEFINE-GPS trial.

The DEFINE-PCI study received funding from Philips/Volcano Corp.

3.2. FORECAST: A randomized trial of CTA/FFR-CT decision-making in patients with chest pain

Presenter: Dr. Nick Curzen

Key Points: An analysis of computed tomography coronary angiography (CTCA) assessment of FFR in UK patients with stable chest pain, recruited for the FORECAST trial, showed the non-invasive procedure in FFR measurement did not significantly reduce overall cardiac medical costs within 9 months compared to routine care.

CTCA did reduce the need for invasive coronary angiography (ICA), which would be “very attractive” to patients, study lead Nick Curzen, PhD, BM (Hons), University of Southampton, said while presenting the results [6]. FFR measurement based on computed tomography (FFR-CT) is a novel, well-validated non-invasive measure to determine the presence and extent of CAD, combined with a physiological assessment of vessel-specific ischemia in patients with chest pain, the researchers note in their abstract. Previous data have suggested FFR-CT could reduce the need for invasive angiography, thereby protecting patient safety. Observational findings from the UK health technology assessment (HTA) body, the National Institute for Health and Care Excellence (NICE), the authority that issues guidance over interventions for reimbursement for the National Health Service (NHS) England and Wales, also suggest that financial savings could be made through use of CTCA and FFR-CT as a frontline strategy. NICE, therefore, already recommends FFR-CT in routine clinical practice, although the clinical effectiveness and economic impact of this compared to other tests in the evaluation of stable chest pain had not previously been tested in a randomized trial.

The FORECAST randomized trial was aimed at addressing this, laying out the economic as well as clinical impact of non-invasive cardiac tests, including FFR-CT compared with routine options such as ICA, coronary revascularization, hospitalization for a cardiac event, and cardiac medications. The primary endpoint was total cardiac medical cost through 9 months. Secondary endpoints included major adverse cardiac or cerebrovascular events (MACCE), revascularization, angina severity, and quality of life. FORECAST recruited 1400 patients in 11 UK centers with new-onset stable chest pain and a mean age of 60 years (ranging from 25 to 89 years), not including angina patients, those with a need for further testing, those with prior coronary revascularization, or those unsuitable for CTCA. The subjects were randomized 1-to-1 to receive either CTCA with FFR-CT or routine assessment under NICE guidelines, including ICA (47, 6.7%), stress echo (103, 14.7%), nuclear perfusion scan (13, 1.9%), CTCA (430, 61.4%), exercise tolerance test (70, 10%), stress magnetic resonance imaging (1, 0.1%), or for 36 of the patients (5.1%), no test.

Of the 700 patients randomized to CTCA with FFR-CT, 675 (96%) underwent CTCA, with 220 (33%) of these patients having a coronary stenosis of 40% or more in at least one major epicardial vessel of a diameter suitable for revascularization given FFR-CT analysis. The 415 (61%) patients with an epicardial lesion not above 40% did not receive FFR-CT, while a further 39 (6%) could not receive this analysis because of quality or technical reasons. The researchers found that 126 of the patients undergoing FFR-CT had at least one vessel with FFR-CT of less than 0.8. The cost in the NHS was not reduced for patients assessed by CTCA with FFR-CT compared to those tested with routine care, at £1605.50 (\$2069.80) versus £1491.46 (\$1926.07), respectively. However, the researchers found that the use of ICA was 22% lower in the test group (136 patients, 19.4%) than in the reference group, in which 175 patients (25%) had to undergo the more invasive procedure. There were also no significant

differences in the rates of MACCE or revascularization between the test and control groups.

The trial was sponsored by University Hospital Southampton.

3.3. TARGET FFR: A randomized trial of physiology-guided PCI optimization

Presenter: Dr. Damien Collison

Key Points: The number of patients found to have suboptimal FFR following PCI in the TARGET FFR trial was “surprisingly” high, according to the lead researcher, although a physiologically guided optimization strategy did improve the rates compared to standard care.

The results of the TARGET FFR trial were reported by Damien Collison, MD, of the Golden Jubilee National Hospital [7]. There is high uncertainty over the number of patients either above the favorable 0.90 threshold for FFR or left still below the 0.80 risk-level following PCI. There are limited data for either outcome in everyday practice, as registry data suggest that the proportion of patients achieving FFR of 0.90 or more post-PCI ranges from 21% to 100%. TARGET FFR, therefore, set out to assess whether a physiologically guided optimization strategy for PCI could achieve a clinically meaningful increase (by 20%) in the proportion of patients who achieve a final post-PCI FFR of 0.90 or more compared to standard care. The secondary measure was the proportion of patients with a final post-PCI FFR result of 0.80 or less.

The researchers randomized 260 patients (1 to 1) between March 2018 and November 2019 following angiographically successful PCI for either stable angina or medically stabilized NSTEMI to receive either a physiology-guided incremental optimization strategy (PIOS) or blinded post-PCI coronary physiology measurements. All patients received a comprehensive invasive coronary physiology assessment both before and after PCI, which incorporated hyperemic and non-hyperemic indices. Patients randomized to PIOS had post-PCI physiology analyses disclosed to the operators, and FFR pullback assessments guided further protocolized optimization measures such as additional post-dilation and/or stenting.

Pre-randomization, the initial angiographically guided post-PCI FFR results were available in 238 of the 260 patients as adjudicated by the core lab. Of those, 32% had FFR of 0.90 or more. A plurality (39%) had FFR rates between 0.81 and 0.89, while 29% still had FFR of 0.80 or less. The rate of final post-PCI FFR of 0.90 or more, the primary endpoint, was 10 percentage points higher for the PIOS group (38.1% vs. 28.1%), but this was not statistically significant ($p=0.099$). However, the proportion of patients with a final FFR score of 0.80 or less was 18.6% in the PIOS group versus 29.8% in the control group, significantly lower at 11.2 percentage points ($p=0.045$). Based on FFR pullback assessment of the stented vessel in the PIOS group, a target for further optimization was found in 60 of the 131 patients (46%). Operators considered it appropriate to perform additional post-dilation core stenting in 40 of these 60 patients. Of those who had further intervention or optimization performed, the mean post-PCI FFR increased from 0.76 to 0.82, with a rise in mean coronary flow reserve (CFR) from 3 to 4.

TARGET FFR did not hit its primary endpoint of achieving an FFR of 0.90 or higher post-PCI with a physiologically guided optimization strategy, but it did significantly increase the proportion of patients with a final FFR of 0.80 or less compared to standard care. Post-PCI FFR values of 0.90 or higher are linked to an improved cardiac prognosis, while the guideline-directed revascularization threshold cited in the study was 0.80 or less. Nevertheless, despite shock aired during the expert panel discussion at the press conference concerning the surprisingly high percentage of patients with suboptimal FFR levels post-PCI, Collison questioned how realistic it is to target 0.90 or more, noting wide variation in PCI practice.

The trial was funded by the UK's NHS National Waiting Times Centre Board endowment funds.

3.4. DEFINE-FLOW: An observational study of deferred lesions after FFR and CFR assessment

Presenter: Dr. Nils Johnson

Key Points: Operators should continue to use the FFR cutoff of ≤ 0.8 in deciding to revascularize a lesion, even with an intact CFR > 2 .

These findings were presented by Nils Johnson, MD, MS, of McGovern Medical School at UT Health (Houston) and Memorial Hermann Hospital, Texas Medical Center [8]. The role of CFR for invasive assessment of coronary lesions currently remains unclear since FFR has become a reference standard (≤ 0.80) decision for revascularization. Prior data have indicated that lesions with intact CFR (≥ 2) do well, but there have not been any larger studies looking at outcomes based on simultaneous assessment by both FFR and CFR. Investigators of the DEFINE-FLOW study sought to answer this question.

This observational study included 455 patients enrolled from 12 sites in six countries. Of those enrolled, 430 patients (533 lesions) were protocol-treated and followed for 2 years. Stable coronary lesions underwent simultaneous FFR and CFR measurement in at least duplicate with central core lab review of the tracings. Treatment followed the local measurements according to a uniform protocol whereby only lesions with both FFR ≤ 0.8 (termed FFR+) and CFR < 2 (CFR+) underwent PCI. All other combinations, including FFR ≤ 0.8 but intact CFR > 2.0 (termed CFR-), received initial medical therapy. FFR > 0.8 was termed FFR-. The primary endpoint was MACE, a composite of all-cause death, myocardial infarction, and any revascularization at 2 years with a non-inferiority margin of 10%.

The study findings for MACE were 5.8% for FFR-/CFR-, 10.8% for FFR+/CFR-, 12.4% for FFR-/CFR+, and 14.4% for FFR+/CFR+ (after PCI). The difference between FFR+/CFR- and FFR-/CFR- was 5.0% (95% CI: -1.5%, 11.5%; $p = 0.065$ for non-inferiority). Therefore, the study found that vessels with abnormal FFR ≤ 0.8 but intact CFR ≥ 2 did not have non-inferior outcomes compared to FFR > 0.8 and CFR ≥ 2 when treated medically. FFR+/CFR- failed to meet noninferiority, meaning that the FFR cutoff still holds, regardless of the CFR reading. These findings are interesting, but given the observational nature of the study, they come with limitations, as subjects and physicians were unblinded in this study.

The DEFINE-FLOW trial was funded by Philips (previously Volcano Corporation).

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Declaration of competing interest

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All other authors – None.

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