BCIS R&D Group Literature Update
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Michael Mahmoudi
Vijay Kunadian
Nick Curzen

PCI in Practice

MOST CONTROVERSIAL... Is PCI beneficial in stable single vessel disease?

Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial
R Al-Lamee et al.
The Lancet 2018; 391:31-40

In patients with stable angina, PCI has been associated with a reduction in the relief of angina but no placebo-controlled trials have been undertaken in this patient population. The ORBITA trial was a multicentre, randomised study of 230 patients designed to assess the effects of PCI versus placebo on exercise time. Key inclusion criteria were patients aged 18-85 years with angina, at least one angiographically significant lesion (≥70% on visual assessment). After enrolment, the study consisted of two consecutive phases: first 6-weeks consisting of optimizing anti-anginal therapy and the second 6 weeks during which patients underwent follow-up assessment including Canadian Cardiovascular Society angina severity, cardipulmonary exercise testing, dobutamine stress echocardiography, blood pressure and heart rate monitoring. At enrolment, patients completed SAW and EQ-5D-5L questionnaire. In all patients, a research invasive FFR and iFR was also undertaken in the PCI group. Of note, the values of the FFR and iFR were not available to the operator making the PCI arm an angiography guided procedure & were negative in some cases. The primary end point of the study was the difference in exercise time increment between the groups. Secondary end points included peak VO2, change in exercise time to 1 mm ST segment depression, angina severity, physical limitation, angina stability and angina frequency. ORBITA demonstrated no significant difference in exercise time increment between the two groups (PCI minus placebo=16.6 seconds; 95% CI:-8.9-42; p=0.2). Similarly, there were no differences between the PCI arm and the placebo arm in any components of the secondary end point. Interestingly, the exercise time did increase significantly in the PCI arm and not in the medical arm, but this was not the prespecified endpoint. The conclusion was that “in patients with medically treated angina and severe coronary stenosis, PCI did not increase exercise time by more than the effect of a placebo procedure”. The debate rages about the trial design but employing a sham arm makes this a powerful study.

Crush better than you thought in LM PCI?

Double Kissing Crush Versus Provisional Stenting for Left Main Distal Bifurcation Lesions

DKCRUSH-V Randomized Trial
S Chen, et al.
J Am Coll Cardiol 2017; 70:2605-17

There are varying PCI techniques for unprotected distal left main (ULM) disease including single stent strategy, provisional T-stenting (PS), crush technique, or culotte. No trial had previously compared DK crush with PS in the context of ULM disease. The DKCRUSH-V randomized trial was a prospective, randomised, international, multicentre study of 482 patients with distal ULM disease scheduled to undergo PCI to evaluate the comparative
outcomes of DK crush with PS. The main inclusion criteria were silent ischemia, stable or unstable angina, MI>24 hours before treatment, distal left lesion (Medina 1,1,1 or 0,1,1) with >50% stenosis of both the ostial Cx and LAD by visual assessment.

The primary end point was target lesion failure defined as the composite of cardiac death, target vessel MI, or clinically driven target lesion revascularization at 1 year follow-up. Secondary end point included all cause death, all MI, periprocedural troponin I release, clinically driven revascularization, angina, and in-stent restenosis. In this study, DK crush was associated with a significantly lower primary end point (5% vs. 10.7%; p=0.02). DK crush was also associated with lower rates of target vessel MI (0.4% vs. 2.9%; p=0.03). Clinically driven target vessel revascularization (3.8% vs. 7.9%; p=0.06) and angiographic restenosis (7.1% vs. 14.6%; p=0.1) were numerically lower with DK crush.

In this randomised trial, DK CRUSH was associated with a superior outcome compared to PS in LM PCI.

**Why do scaffolds thrombose?**

**Mechanisms of Very Late Bioresorbable Scaffold Thrombosis**

K Yamaji, et al.

*J Am Coll Cardiol* 2017; 70:2330-44

Fully bioresorbable coronary scaffolds have the theoretical advantages of reducing the long term risk of device related adverse events such as restenosis and thrombosis as well as avoiding permanent caging of the coronary artery. However, despite the initial favourable results associated with the Absorb bioresorbable vascular scaffold (BVS), a number of studies have indicated that the BVS is associated with greater risks of target vessel myocardial infarction and device thrombosis as compared to second generation drug-eluting stents. The INVEST registry, an independent international consortium of investigators, has been set up to investigate the underlying mechanism(s) of very late BVS thrombosis as assessed by OCT.

Over a period of 4 years, 36 patients with 38 lesions with very late BVS thrombosis underwent OCT. The underlying mechanisms of very late thrombosis were as follows: scaffold discontinuity (42.1%), malapposition (18.4%), neoatherosclerosis (18.4%), underexpansion or scaffold recoil (10.5%), uncovered struts (5.3%), and edge related disease progression (2.6%). Future randomized studies will be required to determine whether novel scaffold designs and optimized implantation techniques can reduce the risk of very late scaffold thrombosis.

**Embolic Protection in SVG Intervention—Not worthwhile after all?**

**Outcomes of Saphenous Vein Graft Intervention With and Without Embolic Protection Device. A Comprehensive Meta-Analysis**

T Paul et al.

*Circ Cardiovasc Interv* 2017; 10:e005538

Despite a class I recommendation for the use of embolic protection devices (EPD) for saphenous vein graft (SVG) intervention, the results of clinical studies have produced conflicting results with regards to this recommendation. Paul et al have undertaken a meta-analysis of 8 studies including 52,893 patients (EPD used in 11,506 patients and EPD not used in 41,387 patients) to compare all-cause mortality, major adverse cardiovascular events (MACE), MI, or target vessel revascularization in patients undergoing SVG PCI with or without EPD.

In this meta-analysis, there were no significant differences in all cause mortality (OR,0.79; CI:0.55-1.12; p=0.19), MACE (OR,0.73; CI:0.51-1.05; p=0.09), late MI (OR,0.80; CI:0.52-1.23; p=0.3), or target vessel revascularization (OR,1.0; CI:0.95-1.05) between the two groups. The lack of differences may be related to potent pharmacotherapy including the use of vasodilator agents to manage no reflow, the use of dual antiplatelet therapy, improved procedural techniques, as well as the availability of less bulky devices.
Based upon these data, the authors have recommended a revision of current recommendations with regard to routine use of embolic protection.

**ACUTE CORONARY SYNDROMES**

**A very old myth debunked!**

**CULPRIT-SHOCK**

H Thiele, et al.


The optimal revascularization strategy in patients presenting with STEMI, multivessel coronary artery disease (CAD), and cardiogenic shock is uncertain. The CULPRIT-SHOCK investigators randomized 706 patients with acute MI (AMI), multivessel CAD and cardiogenic shock to either PCI of the culprit lesion with the option of staged revascularization of non-culprit lesions or immediate multi-vessel PCI including efforts to recanalize chronic total occlusions. Multi-vessel CAD was defined as disease in at least two major vessels ≥2 mm in diameter with >70% stenosis and an identifiable culprit lesion. Cardiogenic shock was defined as systolic blood pressure <90mmHg for longer than 30 minutes or the use of catecholamine therapy to maintain the systolic blood pressure of at least 90mmHG, clinical signs of pulmonary congestion, and signs of impaired organ perfusion with at least one of the following features: altered mental status, cold and clammy skin and limb, oliguria with urine output <30ml/hour or arterial lactate >2nmol/L.

The primary end point of the trial was a composite of death or severe renal failure leading to renal-replacement therapy within 30 days of randomization. Safety end point were bleeding and stroke. At 30 days, the primary end point was significantly lower in patients randomised to culprit lesion PCI (45.9% vs. 55.4%; RR:0.83; 95% CI:0.72-0.98; p=0.01). The relative risk of death in the culprit lesion only PCI was 0.84 (95% CI:0.72-0.98; p=0.03) and the relative risk of renal-replacement therapy was 0.84 (95% CI:0.49-1.03; p=0.07). The risk of bleeding (16.6% vs. 22%; p=0.07) and stroke (3.5% vs. 2.9%; p=0.68) were similar in the two groups.

In this group of patients with cardiogenic shock, culprit lesion PCI is superior to multivessel PCI, a difference that is driven by a lower mortality.

**Early switch back to good old clopidogrel?**

**Benefit of switching dual antiplatelet therapy after acute coronary syndrome: the TOPIC (timing of platelet inhibition after acute coronary syndrome) randomized study**

Thomas Cuisset et al

*European Heart Journal, Volume 38, Issue 41, 1 November 2017, Pages 3070–3078*

The TOPIC trial evaluated the benefit of switching dual antiplatelet therapy (DAPT) from aspirin plus a newer P2Y12 blocker to aspirin plus clopidogrel 1 month after ACS. 645 patients admitted with ACS requiring intervention, on aspirin and a newer P2Y12 blocker and without adverse event at 1 month, were assigned to switch to aspirin and clopidogrel (switched DAPT) or continuation of their drug regimen (unchanged DAPT). The primary outcome was a composite of cardiovascular death, urgent revascularization, stroke and bleeding as defined by the Bleeding Academic Research Consortium (BARC) classification ≥2 at 1 year post ACS. Of the total 645 patients, 322 patients were in the switched DAPT and 323 were in the unchanged DAPT group. The primary endpoint occurred in 13.4% in the switched DAPT group and in 26.3% in the unchanged DAPT (P < 0.01) driven by BARC ≥ 2 bleeding that occurred in 4.0% in the switched DAPT and 14.9% in the unchanged DAPT group (P < 0.01).

The investigators concluded that a switched DAPT is superior to an unchanged DAPT strategy to prevent bleeding complications without increase in ischaemic events following ACS.
An argument for earlier angiography? Roll on RAPID NSTEMI!

**Impact of total occlusion of culprit artery in acute non-ST elevation myocardial infarction: a systematic review and meta-analysis**

Abdur R. Khan et al

*European Heart Journal, Volume 38, Issue 41, 1 November 2017, Pages 3082–3089*

This was a meta-analysis to estimate the difference in outcomes between totally occluded and non-occluded culprit arteries in patients with NSTEMI. 40 777 patients from 7 studies were included. The outcomes assessed were clinical presentation (Killip class), left ventricular ejection fraction, time to angiography, major cardiac adverse events (MACE) and all-cause mortality. 25.5% patients had an occluded culprit artery (40% right coronary and 33% left circumflex artery). There was an increased risk of both MACE (short-term, \(P = 0.0003\); medium- to long-term, \(P = 0.001\)) and all-cause mortality (short-term \(P < 0.0001\); medium to long-term \(P = 0.01\)) with total occlusion of the culprit artery.

This meta-analysis suggests that patients with NSTEMI who have a totally occluded culprit vessel on coronary angiography are at higher risk of mortality and major adverse cardiac events.

**MULTIVESSEL REVASCULARISATION**

**Is PCI getting better?**

*Clinical outcomes of state-of-the-art percutaneous coronary revascularization in patients with de novo three vessel disease: 1-year results of the SYNTAX II study*

Javier Escaned et al

*European Heart Journal, Volume 38, Issue 42, 7 November 2017, Pages 3124–3134*

The SYNTAX II investigators sought to evaluate if recent technical and procedural developments in percutaneous coronary intervention (PCI) influence clinical outcomes in patients with three-vessel (3VD) coronary artery disease in this multicentre study conducted in 22 centres from 4 European countries. The SYNTAX-II strategy included: heart team decision-making utilizing the SYNTAX Score II, coronary physiology-guided revascularisation, implantation of thin strut bioresorbable-polymer drug-eluting stents, intravascular ultrasound (IVUS)-guided stent implantation, contemporary chronic total occlusion revascularisation techniques and guideline-directed medical therapy. MACCE consisted of composite of all cause death, cerebrovascular event, any myocardial infarction and any revascularisation at one year was compared to a predefined PCI cohort and the historical CABG cohort of the original SYNTAX-I trial. 454 patients of 708 screened underwent PCI. At one year, the SYNTAX-II strategy was superior to the equipoise-derived SYNTAX-I PCI cohort (MACCE SYNTAX-II 10.6% vs. SYNTAX-I 17.4%; \(P = 0.006\)). This difference was driven by a significant reduction in the incidence of MI (\(P = 0.007\)) and revascularisation (\(P = 0.015\)). Rates of all-cause death and stroke (\(P = 0.71\)) were similar. The rate of definite stent thrombosis was significantly lower in SYNTAX-II (\(P = 0.045\)).

Thus, the clinical outcomes with the SYNTAX-II strategy were associated with better clinical results compared to the PCI performed in the original SYNTAX-I trial.
OLDER PATIENTS

Good news for DES in the elderly

DES or BMS for SENIORS
O Varenne, et al.
The Lancet 2018; 391:41-50

The optimal PCI strategy for elderly patients remains ill defined as many such patients have been excluded from landmark PCI studies purely based upon their age criteria. The prevalence of elderly patients are increasing, they often have complex coronary artery disease, and are at increased risk of bleeding from dual antiplatelet therapy. The SENIOR trial is a randomised, single blind, multicentre study of 1200 patients aged ≥75 years presenting with stable angina, silent ischemia, or an acute coronary syndrome including STEMI, and whom had at least one coronary stenosis of at least 70% severity (≥ for the left main) deemed eligible for PCI that were randomised to PCI with either the bioabsorbable polymer DES (SYNERGY, Boston Scientific)) or a BMS (Omega or Rebel; Boston Scientific). Of note, the duration of dual antiplatelet therapy was 1 month in stable or silent cases and 6 months in unstable cases in both groups.

The primary end point was the cumulative incidence of major adverse cardiac and cerebrovascular events (MACCE) defined as a composite of all-cause mortality, MI, ischaemic driven target lesion revascularization, or stroke at 1 year. Key secondary end points included bleeding complications, and definite or probable stent thrombosis. In this study, the rate of MACCE was significantly lower in the DES group (12% vs. 16%; RR:0.71; 95% CI:0.52-0.94; p=0.02). Bleeding complications (5% vs. 5%; p=0.68), and stent thrombosis (1% vs. 1%; p=0.13) were similar in both groups.

The SENIOR trial indicates that in patients aged ≥75 years undergoing PCI, a strategy of PCI with the SYNERGY stent and short duration of dual antiplatelet therapy is safe and efficacious as compared to a BMS.

Counter-ageism?

Revascularisation compared with initial medical therapy for non-ST-elevation acute coronary syndromes in the elderly: a meta-analysis
Sonali R Gnanenthiran et al
Heart 2017; 103 1932-1933

This meta-analysis compared routine invasive therapy with initial medical management in the older patients (≥75 years) presenting with NSTEACS. Endpoints included long-term mortality, myocardial infarction (MI), revascularisation, rehospitalisation, stroke and major bleeding reported as ORs. 4 randomised trials and 3 observational studies met inclusion criteria, enrolling a total of 20 540 patients followed up from 6 months to 5 years. Analyses restricted to randomised controlled trials (RCTs) confirmed a reduction in myocardial infarction (Odds Ratio 0.51, Confidence Interval 0.40-0.66), revascularisation (OR 0.27, CI 0.13-0.56) and a trend to reduced mortality (OR 0.84, CI 0.66-1.06) at the expense of major bleeding (OR 2.19, CI 1.12-4.28) in the invasive group compared to the conservative group. The authors concluded that routine invasive therapy reduces myocardial infarction and repeat revascularisation and may reduce mortality at the expense of major bleeding in older patients with NSTEACS.
**VALVULAR HEART DISEASE**

**Not what we expected?**

*Emergency treatment of decompensated aortic stenosis*

Dario Bongiovanni et al
*Heart* 2018;104:23–29

Bongiovanni and colleagues assessed the early outcome of emergency transcatheter aortic valve implantation (eTAVI) versus emergency balloon aortic valvuloplasty (eBAV) followed by TAVI under elective circumstances. The authors defined emergency conditions as: cardiogenic shock with requirement of catecholamine therapy, severe acute dyspnoea (NYHA IV), cardiac resuscitation or mechanic respiratory support. In 5 German centres, 23 patients (logistic Euroscore 37.7%±18.1) underwent eTAVI and 118 patients underwent eBAV (logistic Euroscore 35.3%±20.8). In the eTAVI group, immediate procedural mortality was 8.7%, compared with 20.3% for the eBAV group (p=0.19). After 30 days, cardiovascular mortality for the eTAVI group was 23.8% and for the eBAV group 33.0% (p=0.40). Of note, the elective TAVI performed after eBAV (n=32, logistic Euroscore 25.9%±13.9) displayed an immediate procedural mortality of 9.4% and a cardiovascular mortality after 30 days of 15.6%. Major vascular complications were significantly more likely to occur after eTAVI (p=0.01) as well as stroke (p=0.01).

In this multicentre cohort, the immediate procedural and 30-day mortality of eTAVI and eBAV were high, and mortality of secondary TAVI subsequent to eBAV was higher than expected.

**Conscious Sedation for TAVR definitely a good thing**

*Conscious Sedation Versus General Anesthesia for Transcatheter Aortic Valve Replacement. Insights from the National Cardiovascular Data Registry Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry.*

M Hyman, et al.
*Circulation* 2017; 136:2132-2140

Despite the increasing use of conscious sedation in patients undergoing TAVR, the evidence base for this practice is limited. Hyman et al examined the National Cardiovascular Data Registry Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry between April 2014-June 2015 to characterize the choice of anaesthesia (conscious sedation versus general anaesthesia) in patients undergoing elective TAVR and compare in-hospital mortality, 30-day mortality, in-hospital and 30-day death/stroke, procedural success, ITU and hospital length of stay, and rates of discharge to home.

In this registry, conscious sedation was used in 15.8% of cases. Conscious sedation was associated with significantly lower rates of in hospital mortality (1.6% vs. 2.5%; p=0.03), 30 day mortality (2.9% vs. 4.1%; p=0.03), ITU and hospital length of stay (6 days vs. 6.5 days; p<0.001), combined 30 day death/stroke (4.8% vs. 6.4%; p<0.001). The rates of vascular complications, bleeding, and pacemaker implantation were similar in the two groups.

These results indicate that conscious sedation is safe and may be associated with potential cost savings.

**Most surprising result this month?**

*Mechanical aortic valve replacement in non-elderly adults: meta-analysis and microsimulation*

Nelleke M Korteland et al
*European Heart Journal, Volume 38, Issue 45, 1 December 2017, Pages 3370–3377*

Korteland et al sought to provide a detailed overview of outcome after contemporary mechanical aortic valve replacement (AVR) in young patients. They undertook a systematic review of studies (29 publications, 5728 patients with 32 515 patient-years of follow-up = pooled mean follow-up: 5.7 years) reporting clinical outcome after AVR with bileaflet
mechanical valves with a mean patient age $\geq$18 and $\leq$55 years. Mean age at surgery was 48 years. Early mortality risk was 3.15%, late mortality rate was 1.55%/year with 38.7% of late deaths were related to valve. Thromboembolism rate was 0.90%/year, major bleeding 0.85%/year, non-structural valve dysfunction 0.39%/year, endocarditis 0.41%/year, valve thrombosis 0.14%/year and reintervention 0.51%/year, mostly due to non-structural valve dysfunction and endocarditis. This translated to an estimated life expectancy of 19 years for a 45-year-old compared with the general population of 34 years and lifetime risks of thromboembolism, bleeding and reintervention of 18%, 15%, and 10%, respectively.

The outcome after mechanical AVR in young adults is characterized by suboptimal survival and considerable lifetime risk of anticoagulation-related complications, and also reoperation.

Intuitive but still useful?

**Staging classification of aortic stenosis based on the extent of cardiac damage**

Philippe Généreux et al

*European Heart Journal, Volume 38, Issue 45, 1 December 2017, Pages 3351–3358*

This study evaluated the prognostic impact of a newly defined staging classification characterising the extent of extra-aortic valve cardiac damage among patients with severe aortic stenosis (AS) undergoing aortic valve replacement (AVR). The investigators pooled data from 1661 patients with severe AS from the PARTNER 2 trials and classified them according to the presence or absence of cardiac damage as detected by echocardiography prior to AVR: Stage 0- No extravalvular cardiac damage (2.8%); Stage 1- Left ventricular damage (12.8%); Stage 2- Left atrial or mitral valve damage (50.8%); Stage 3- Pulmonary vasculature or tricuspid valve damage (24.9%) and Stage 4- Right ventricular damage (8.7%). One-year mortality was 4.4% in Stage 0, 9.2% in Stage 1, 14.4% in Stage 2, 21.3% in Stage 3, and 24.5% in Stage 4 ($P_{\text{trend}} < 0.0001$). The extent of cardiac damage was independently associated with increased mortality after AVR ($P < 0.0001$).

The authors concluded that this new staging classification objectively characterises the extent of cardiac damage associated with AS and has important prognostic implications for clinical outcomes after aortic valve replacement.

**IMAGING**

An angiogram-derived alternative to FFR for physiology? The start of an avalanche of similar systems

**Diagnostic Accuracy of Angiography-Based Quantitative Flow Ratio Measurements for Online Assessment of Coronary Stenosis.**

B Xu, et al.

*J Am Coll Cardiol* 2017; 70:3077-87

Despite the wealth of evidence in support of FFR–guided management strategy, the adoption of FFR remains at best modest in part due to cost, concerns regarding the adverse effects of adenosine, and wire related complications. Quantitative flow ratio (QFR) has emerged as a novel method for evaluation of FFR based upon 3-dimensional angiographic reconstruction and fluid dynamics algorithms. The FAVOR II China study is a prospective, multicentre trial of 308 consecutive patients who had at least 1 lesion with a stenosis of 30-90% severity and a reference diameter $\geq$2mm based on visual assessment and measured QFR, quantitative coronary angiography (QCA), and wire based FFR (RadiAnalyzer Xpress instrument and Certus pressure wire with adenosine-5-triphosphate as the vasodilator) were assessed online in a blinded fashion during coronary angiography and reanalysed offline at an independent core laboratory.

The primary end point of the study was that QFR would improve the diagnostic accuracy of coronary angiography. Patient and vessel-level diagnostic accuracy of QFR was 92.4% (95% CI:88.9%-95.1%) and 92.7% (95% CI:89.3%-95.3%), both of which were above the prespecified target value of 75% ($p<0.001$). Sensitivity and specificity in identifying
hemodynamically significant stenosis defined as FFR ≤0.8 were significantly higher for QFR than QCA (sensitivity: 94.6% vs. 62.5%; P<0.001; specificity 91.7% vs. 58.1%; p<0.001). Positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio for QFR were 85.5%, 97.1%, 11.4 and 0.06 respectively.

The study has concluded that QFR is a feasible and accurate method for identifying significant coronary stenosis during coronary angiography.

What can we do about this?

Relationship between microvascular obstruction and adverse events following primary percutaneous coronary intervention for ST-segment elevation myocardial infarction: an individual patient data pooled analysis from seven randomized trials
Suzanne de Waha et al
European Heart Journal, Volume 38, Issue 47, 14 December 2017, Pages 3502–3510
This study evaluated the relationship between microvascular obstruction (MVO) and all cause mortality, hospitalization for heart failure, and reinfarction following primary percutaneous coronary intervention (PPCI) in STEMI. 1688 patients from 7 randomized PPCI trials in which MVO was assessed using late gadolinium enhancement cardiac MRI (CMR) within 7 days after reperfusion were evaluated. Median time to CMR after STEMI was 3 days, and median duration of clinical follow-up was 365 days. MVO was present in 56.9% of patients. The authors demonstrated that the extent of MVO (per 1.0% absolute increase) was associated with subsequent mortality and hospitalization for heart failure (P<0.0001). MVO remained significantly associated with all-cause mortality even after further adjustment for infarct size (P = 0.03) but not significantly related to subsequent reinfarction (P = 0.29).

The presence and extent of MVO measured by CMR after PPCI in STEMI were strongly associated with mortality and hospitalization for heart failure within 1 year.

New imaging or any imaging?

Optical frequency domain imaging vs. intravascular ultrasound in percutaneous coronary intervention (OPINION trial): one-year angiographic and clinical results
Takashi Kubo et al
European Heart Journal, Volume 38, Issue 42, 7 November 2017, Pages 3139–3147
This was a multicentre, randomised study designed to test the non-inferiority of Optical frequency domain imaging (OFDI)-guided PCI compared with Intravascular ultrasound (IVUS)-guided PCI in terms of clinical outcomes. The primary endpoint was target vessel failure defined as a composite of cardiac death, target-vessel related myocardial infarction, and ischaemia-driven target vessel revascularization until 12 months after the PCI. 829 patients were randomly allocated to receive OFDI-guided PCI (n = 414) or IVUS-guided PCI (n = 415). Target vessel failure occurred in 5.2% patients undergoing OFDI-guided PCI, and 4.9% patients undergoing IVUS-guided PCI, demonstrating non-inferiority of OFDI-guided PCI to IVUS-guided PCI (Pnon-inferiority = 0.042).

In this study the 12-month clinical outcome in patients undergoing OFDI-guided PCI was non-inferior to that of patients undergoing IVUS-guided PCI.