Interventional Cardiology Research Review™

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In this issue:

Abbreviations used in this issue:

ACS = acute coronary syndrome; **CABG** = coronary artery bypass graft; **CAD** = coronary artery disease; **DAPT** = dual antiplatelet therapy; **DES** = drug-eluting stent; **FFR** = fractional flow reserve; **IVUS** = intravascular ultrasound; **LIMA** = left internal mammary artery; **MI** = myocardial infarction; **NSTEACS/NSTEMI/STEMI** = (non-)ST-segment elevation ACS/MI; **OR** = odds ratio; **PCI** = percutaneous coronary intervention; **TAVR** = transcatheter aortic valve replacement.

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Welcome to issue 34 of Interventional Cardiology Research Review.

We begin this issue with a study comparing outcomes of transradial versus transfemoral diagnostic catheterisation and/or PCI in patients who have previously undergone CABG. This is followed by a trial reporting that management of STEMI is more difficult and outcomes are worse in patients who have previously undergone TAVR. The selection also includes a report in the N Engl J Med from the FLOWER-MI trial, which compared an FFR-guided strategy with an angiography-guided strategy in patients with STEMI undergoing complete revascularisation. The issue concludes with a trial reporting that a fixed-wire, rapid exchange bioresorbable-polymer sirolimus-eluting coronary stent system (SVELTE) failed to meet noninferiority criterion compared with a durable-polymer everolimus-eluting stent, with unexpectedly higher rates of target-vessel MI.

We trust that the research selected provides you with valuable takeaway information you can use in your everyday practice. We look forward to your comments and feedback.

Kind Regards,

Conjoint Professor Craig Juergens
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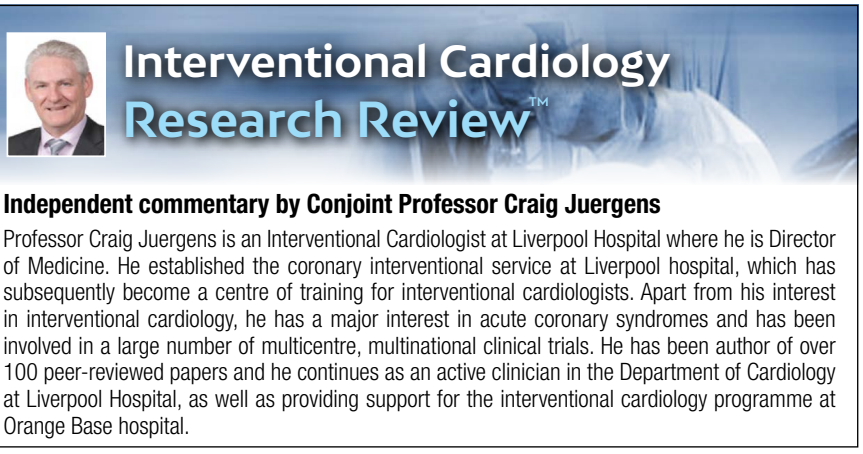
Characteristics and outcomes of patients with history of CABG undergoing cardiac catheterization via the radial versus femoral approach

Authors: Manly DA et al.

Summary: These researchers reported on diagnostic catheterisations and PCIs undertaken in 1,279,058 patients from 1173 sites, entered in the US CathPCI registry, who had previously undergone CABG. There was an increase in the transradial access rate over the study period (2009–2018) from 1.4% to 18.7%. There were significant associations of transradial access with reduced mortality (adjusted OR 0.83 [95% CI 0.75–0.91]), less bleeding (0.57 [0.51–0.63]), fewer vascular complications (0.38 [0.30–0.47]), increased PCI procedural success (1.11 [1.06–1.16]), decreased contrast volume (all procedure types), shorter fluoroscopy times for PCI-only procedures, and longer fluoroscopy times for diagnostic procedures plus *ad hoc* PCI and diagnostic procedures only. Transradial access was more likely to be undertaken by operators with a higher transradial access rate in non-CABG patients.

Comment: The use of the radial artery to perform coronary angiography has been shown to reduce bleeding and vascular complications, but patients who have previously undergone CABG are under-represented in these trials. The current study used data from the large-scale US CathPCI registry. Notably, patients with STEMI or shock were excluded, but the authors showed that the use of radial access is increasing, although only in 18.7% of cases. As with non-CABG cases, radial access was associated with improved outcomes in this nonrandomised observational study. There are practical issues in performing the procedure when the left radial artery has been used as a conduit and the LIMA graft needs to be engaged; however when present and accessed, this can actually make the procedure easier in terms of engaging a LIMA graft. This study supports the notion that in the majority of CABG patients a radial first strategy should also be considered.

Reference: JACC Cardiovasc Interv 2021;14:907–16
Abstract



Independent commentary by Conjoint Professor Craig Juergens

Professor Craig Juergens is an Interventional Cardiologist at Liverpool Hospital where he is Director of Medicine. He established the coronary interventional service at Liverpool hospital, which has subsequently become a centre of training for interventional cardiologists. Apart from his interest in interventional cardiology, he has a major interest in acute coronary syndromes and has been involved in a large number of multicentre, multinational clinical trials. He has been author of over 100 peer-reviewed papers and he continues as an active clinician in the Department of Cardiology at Liverpool Hospital, as well as providing support for the interventional cardiology programme at Orange Base hospital.

ST-segment elevation myocardial infarction following transcatheter aortic valve replacement

Authors: Faroux L et al.

Summary: This study evaluated the management of STEMI in 118 patients with previous TAVR versus 439 with STEMI without previous TAVR; all patients underwent PCI. Median door-to-balloon time was higher in patients with previous TAVR (40 vs. 30 min), as were procedural time, fluoroscopy time, dose-area product and contrast volume (p<0.01 for all). PCI failure was more common in patients with previous TAVR (16.5% vs 3.9% [p<0.001]). The incidences of in-hospital and late mortality were 25.4% and 42.4%, respectively, in TAVR patients, compared with 20.6% and 38.2% in non-TAVR patients.

Comment: TAVR has become the predominant treatment modality for severe aortic stenosis, and as data accumulate, it is being used in younger patients. There are limited data about the outcomes of patients who have an STEMI after having undergone TAVR. This paper provides a detailed analysis of 118 patients from a large multicentre, multinational study of TAVR patients. A non-atherothrombotic mechanism such as coronary embolism was the cause in ~15% of cases, and 34.7% of STEMIs occurred within 1 month of the TAVR, despite nearly all having undergone preprocedure coronary angiography. The majority of patients underwent primary PCI, but procedures were longer with more radiation exposure and contrast use than a comparable non-TAVR cohort. There was a high 16.5% PCI failure rate, probably due to difficulties in accessing the coronary arteries. Although the incidence of STEMI was low (0.28%), it was associated with increased in-hospital and 30-day mortality rates. We should continue to aggressively treat cardiac risk factors in these patients and develop newer techniques to facilitate coronary access in these challenging patients.

Reference: J Am Coll Cardiol 2021;77:2187–99
Abstract

International prospective registry of acute coronary syndromes in patients with COVID-19

Authors: Kite TA et al., on behalf of the International COVID-ACS Registry Investigators

Summary: Demographics, angiographic findings and in-hospital outcomes were compared between patients who underwent invasive coronary angiography for suspected ACS who had also contracted COVID-19 and those from two pre-COVID-19 cohorts, namely MINAP (Myocardial Ischaemia National Audit Project) 2019 and BCIS (British Cardiovascular Intervention Society) 2018–2019; 144 patients had STEMI and 121 had NSTEACS. Median symptom-to-admission time was longer in STEMI patients with COVID-19 compared with the BCIS cohort (339.0 vs. 173.0 min [p<0.001]) and in NSTEACS patients with COVID-19 compared with the MINAP cohort (417.0 vs. 295.0 min [p=0.012]), as were mortality rates (22.9% vs. 5.7% [p<0.001] and 6.6% vs. 1.2% [p<0.001], respectively; adjusted OR 3.33 [95% CI 2.04–5.42] in the STEMI subgroup). STEMI patients with COVID-19 had a higher incidence of cardiogenic shock than the BCIS cohort (20.1% vs. 8.7% [p<0.001]).

Comment: COVID-19 has impacted all aspects of our lives and it has become clear there are changes to the way patients with ACS present and are managed. The international COVID-ACS registry is a prospective, observational study of patients with suspected or confirmed COVID-19 conducted at 55 centres across five continents in early 2020. All patients underwent invasive coronary angiography, and patient outcomes were compared with two pre-COVID-19 British registries. The investigators found significant treatment delays for both STEMI and NSTEMI patients. Patients seemed to be sicker with more cardiogenic shock and had increased in hospital mortality and stroke, despite a nonobstructive lesion found in 18.2% of patients.. They also showed primary PCI is feasible although no doubt more ergonomically challenging and should remain the treatment of choice. Despite patients' concerns, we should encourage them to present to hospital when unwell so they can be treated expeditiously.

Reference: J Am Coll Cardiol 2021;77:2466–76
Abstract

Multivessel PCI guided by FFR or angiography for myocardial infarction

Authors: Puymirat E et al., for the FLOWER-MI Study Investigators

Summary: This analysis of the FLOWER-MI study evaluated whether multivessel PCI guided by FFR is superior to an angiography-guided procedure in patients with STEMI; 1163 patients with STEMI and multivessel disease who had undergone successful PCI of the infarct-related artery were randomised 1:1 to receive complete revascularisation guided by either FFR or angiography. The primary outcome was a composite of death from any cause, nonfatal MI or urgent revascularisation at 1 year. The mean number of stents placed per patient for nonculprit lesions was 1.01 in the FFR-guided group and 1.50 in the angiography-guided group. During follow-up, a primary outcome event occurred in 5.5% of patients in the FFR-guided group and 4.2% of patients in the angiography-guided group (hazard ratio 1.32 [95% CI 0.78–2.23]).

Comment: Up to 50% of patients presenting with STEMI have multivessel disease, and recent trials have examined whether the nonculprit vessels should be treated and when. Meta-analyses have shown a 31% lower risk of composite cardiovascular-related death or MI when PCI on nonculprit vessels is performed. Differing studies have used FFR or angiography to guide PCI of nonculprit lesions. The current investigator-initiated multicentre study from France randomised patients to undergo either FFR or angiographic-guided PCI of nonculprit vessels. Notably, 95% of procedures were staged, with a mean time delay of 2.6 days. Whilst FFR guidance reduced the number of additional stented lesions, it resulted in a numerically higher event rate, largely driven by an increase of subsequent MIs in the FFR group. It would appear in this setting, using FFR to guide intervention may be necessary, and we can rely of the trained eye of the interventional cardiologist to guide the need for further revascularisation.

Reference: N Engl J Med 2021;385:297–308
Abstract

Management and outcomes of cardiogenic shock in cardiac ICUs with versus without shock teams

Authors: Papolos AI et al., on behalf of the Critical Care Cardiology Trials Network Investigators

Summary: Practice patterns and outcomes were explored for 1242 admissions for cardiogenic shock to one of 24 North American cardiac intensive care units during 2017–2019, comparing units with (ten centres; 44% of admissions) versus without shock teams. Compared with centres without shock teams, those with shock teams used more pulmonary artery catheters (60% vs. 49%; adjusted OR 1.86 [95% CI 1.47–2.35]) and less overall mechanical circulatory support (35% vs. 43%; 0.74 [0.59–0.95]) but more advanced types as opposed to intra-aortic balloon pumps (53% vs. 43%; 1.73 [1.19–2.51]), and they had a lower mortality rate (23% vs. 29%; 0.72 [0.55–0.94]).

Comment: Primary PCI for STEMI has revolutionised the management of these patients, and it became clear that a well-organised team achieves the best outcomes. Traditionally, patients in cardiogenic shock were treated with timely revascularisation with possibly an intra-aortic balloon pump and we hoped for the best. Consequently, the mortality for this condition has stayed around 50%. The recent advent of mechanical circulatory support, including ECMO (extracorporeal membrane oxygenation) and devices such as the Impella® (Abiomed), have provided hope that we can improve outcomes. As this is very resource-intensive, multidisciplinary 'shock teams' have been created with input from emergency department physicians, interventional cardiologists, intensivists, anaesthetists and cardiothoracic surgeons, amongst others. The current study reported outcomes of patients managed in 'shock team' hospitals versus those without, from the multicentre Critical Care Cardiology Trials Network in North America. Whilst an observational, nonrandomised study, the paper supports the concept, and we should consider forming such networks in our individual hospitals to try and improve outcomes.

Reference: J Am Coll Cardiol 2021;78 1309–17
Abstract

Randomized comparison between radial and femoral large-bore access for complex percutaneous coronary intervention

Authors: Meijers TA et al.

Summary: Patients scheduled for PCI of complex coronary lesions (including chronic total occlusion, left main, heavy calcification or complex bifurcation; n=388) were randomised to transradial access or transfemoral access via 7Fr catheters in this prospective international trial; crossover rates from radial to femoral and from femoral to radial access were 3.6% and 2.6%, respectively. Compared with transfemoral access, transradial access was associated with a significantly lower incidence of access site-related clinically significant bleeding or vascular complications requiring intervention at discharge (primary endpoint; 3.6% vs. 19.1% [p<0.001]), with no significant difference for procedural success rate (86.0% vs. 89.2% [p=0.285]), procedural duration, contrast volume or radiation dose.

Comment: A radial first approach to noncomplex coronary intervention is well supported by large-scale clinical trials, but there has been some reluctance to use radial access in scenarios where larger bore arterial access is required including complex chronic total occlusion or heavily calcified lesions. New developments including thin-walled radial introducer sheaths and sheath-less guiding catheters means 7Fr access is more feasible. The current international, multicentre randomised trial compared radial and femoral access using 7Fr guides. Radial access was superior in terms of bleeding and vascular access-site complications, largely driven by a reduction in the relatively soft endpoint of BARC 2 bleeding (16.5% vs. 3.6% [p<0.001]). Procedural success and need for access site crossover were similar. There was a numerically higher major adverse cardiac event rate at 30 days in the radial group (6.7% vs. 2.6% [p=0.06]), which is concerning, and larger adequately powered trials are needed before this approach becomes the standard of care in patients undergoing complex interventional procedures.

Reference: JACC Cardiovasc Interv 2021;14:1293–303
Abstract

1-month dual-antiplatelet therapy followed by aspirin monotherapy after polymer-free drug-coated stent implantation

Authors: Hong S-J et al., for the One-Month DAPT Investigators

Summary: The One-Month DAPT trial randomised patients with CAD considered for PCI for noncomplex lesions to 1-month DAPT followed by aspirin monotherapy after polymer-free drug-coated stent implantation (n=1507) or 6- to 12-month DAPT after biodegradable-polymer DES implantation (n=1513). Noninferiority was evident between the 1-month versus 5- to 12-month DAPT arms for the composite primary endpoint of cardiac-related death, nonfatal MI, target-vessel revascularisation, stroke or major bleeding (5.9% vs. 6.5% [p<0.001 for noninferiority]), with no significant difference for major bleeds (1.7% vs. 2.5% [p=0.136]) or stent thromboses (0.7% vs. 0.8% [p=0.842]).

Comment: Although DAPT remains the standard of care after PCI with DESs, recent studies have looked to try and decrease the duration of DAPT to reduce the risk of bleeding. The current study from 23 centres in South Korea compared 1 month of DAPT in patients receiving the polymer free biolimus drug-coated BioFreedom™ (Biosensors) stent with 6–12 months of DAPT in those receiving either a biodegradable polymer BioMatrix™ (Biosensors) or Ultimaster™ (Terumo) sirolimus-eluting stent. The results suggest noninferiority of the 1-month group, with no difference in major bleeding or stent thrombosis. The patients were not a high bleeding risk population undergoing noncomplex PCI. There were patients enrolled with ACS (unstable angina pectoris 35%, acute MI 3%), and there seemed to be a safety signal in the shortened-DAPT duration group suggesting we should be careful in this cohort if they are not at high bleeding risk. We should also consider this to be a stent and DAPT duration specific study rather than make generic conclusions.

Reference: JACC Cardiovasc Interv 2021;14:1801–11
Abstract

ACTIVATION (percutaneous coronary intervention prior to transcatheter aortic valve implantation)

Authors: Patterson T et al., on behalf of the ACTIVATION Trial Investigators

Summary: Patients with severe symptomatic aortic stenosis and significant CAD with Canadian Cardiovascular Society class ≤2 angina (n=235) were randomised to PCI or no PCI prior to TAVR in this noninferiority trial. The noninferiority criterion was not met, with 41.5% and 44.0% of the PCI and non-PCI arms experiencing a primary composite endpoint event (all-cause death or rehospitalisation) at 1 year (p=0.067 for noninferiority; p=0.05 for noninferiority in an as-treated analysis). The respective mortality rates in the PCI and non-PCI arms were 13.4% and 12.1%, and there was no significant between-group difference at 1 year for the rate of stroke, MI or acute kidney injury. The PCI arm had a higher any bleeding rate than the non-PCI arm (p=0.021).

Comment: CAD is very prevalent in patients undergoing TAVR, and is known to be a predictor of adverse outcomes, but the management of this is unclear. Current guidelines suggest PCI is reasonable for critical lesions in proximal coronary arteries before TAVR. The current study is the first multicentre randomised controlled trial designed to compare systematic PCI versus no PCI in patients with ≥1 stenosis ≥70% in a major epicardial artery or ≥50% in a protected left main or vein graft. It was a noninferiority design conceived in 2011, and was stopped early due to slow and prolonged recruitment. There appears to be no advantage of routine PCI (median 41 days) before TAVR and there was some harm via an increased bleeding risk (1-year major bleed, 26.1% vs. 18.1%) possibly related to increased DAPT in this population. Future work is needed to assess the role of PCI in a younger population cohort using modern prostheses with consideration of physiologically guided PCI in noncritical lesions.

Reference: JACC Cardiovasc Interv 2021;14:1965–74
Abstract

Impact of intravascular ultrasound on outcomes following percutaneous coronary intervention for in-stent restenosis (iOPEN-ISR study)

Authors: Shlofmitz E et al.

Summary: These researchers reported on 1522 patients with 1-year follow-up following treatment for in-stent restenosis according to IVUS use; 65.9% were treated with IVUS guidance. Compared with patients treated with angiography guidance, those in whom IVUS guidance was used had a lower 1-year major cardiac adverse event rate (primary endpoint; composite of all-cause mortality, Q-wave MI and target-vessel revascularisation; 18.0% vs. 24.5% [p=0.0014]). IVUS was also used more frequently following dilatation (18.6% vs. 14.1% [p<0.001]), with a larger new stent diameter (3.04 vs. 2.94mm [p=0.001]), and was associated with a lower 1-year target-vessel revascularisation rate (14.5% vs. 19.2% [p=0.021]).

Comment: Despite improved technology, in-stent restenosis of DESs occurs in up to 12% of cases. Whilst the use of IVUS to determine the mechanism of such stent failure is recommended, there are limited data to prove its impact on outcomes. This observational analysis from a large registry of patients treated at the Washington Hospital Centre in the USA provides such information, revealing that patients in whom IVUS was used (65.9%) had better outcomes. The decision to use IVUS and treatments instituted were at the operators' discretion, meaning some bias was unavoidable. IVUS use resulted in a minor increase in contrast volume (<8%) and procedure time (<9 min) but a reduced length of stay. There are ongoing randomised studies in this space that will further inform us, but in the meantime, it would appear that intracoronary imaging in patients with in-stent restenosis is beneficial.

Reference: Int J Cardiol 2021;340:17–21
Abstract

Safety and effectiveness of the SVELTE fixed-wire and rapid exchange bioresorbable-polymer sirolimus-eluting coronary stent systems for the treatment of atherosclerotic lesions

Authors: Kereiakes DJ et al.

Summary: The OPTIMIZE study randomised 1639 patients with NSTEMI or stable CAD scheduled for PCI to a fixed-wire and rapid exchange bioresorbable-polymer sirolimus-eluting coronary stent or a durable-polymer everolimus-eluting coronary stent (control). Compared with the everolimus-eluting stent, use of the investigational sirolimus-eluting stent was associated with a higher 12-month target lesion failure rate (10.3% vs. 9.5% [p=0.034]), with similar rates of clinically indicated target lesion revascularisations (1.5% vs. 1.9% [p=0.57]) and stent thromboses (0.38% vs. 0.51% [p=0.72]), but a higher rate of protocol-defined target vessel MI (9.4% vs. 8.2%) at sites that utilised troponin rather than creatine kinase myocardial band assays.

Comment: Stent technologies continue to evolve, but even smaller profile stents may facilitate smaller guiding catheter use in radial procedures. This prospective, randomised, single-blind, multicentre study evaluated the ultralow profile SVELTE sirolimus-eluting stent, which utilises two delivery platforms. One uses the integrated delivery stent system, which is effectively a 'stent on a wire' avoiding the need for conventional guidewires and predilatation and allows direct stenting of lesions. The integrated delivery stent system has a 0.031'' crossing profile deliverable through a ≥4Fr guiding catheter. Notably, lesions in the study had to be ≤24mm in length, ≤90% stenosis, ≤90° angulation with less than moderate calcification. The study did not meet its noninferiority threshold, likely driven by a higher than anticipated incidence of periprocedural troponin elevations (>3 times the upper level of normal), which is of questionable significance. There was a low overall 1-year rate of cardiac-related death (0.25%), target lesion revascularisation (1.5%) and stent thrombosis (0.38%) with this technology, meaning this stent may have a place in select patient subgroups.

Reference: Circ Cardiovasc Interv 2021;14:e010609
Abstract

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