Interventional Cardiology Research Review™

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In this issue:

Abbreviations used in this issue:

CABG = coronary artery bypass graft; **CTO** = chronic total occlusion; **CV** = cardiovascular; **DAPT** = dual antiplatelet therapy; **DCB** = drug-coated balloon; **DES** = drug-eluting stent; **HR** = hazard ratio; **IVUS** = intravascular ultrasound; **LMWH** = low-molecular-weight heparin; **OR** = odds ratio; **PCI** = percutaneous coronary intervention; **RCT** = randomised controlled trial; **SAVR/TAVI/TAVR** = surgical/transcatheter aortic valve implantation/replacement; **STEMI** = ST-segment elevation MI.

Welcome to issue 37 of Interventional Cardiology Research Review.

We begin this issue with a study from the US reporting trends and outcomes following *ad hoc* PCI according to whether it was performed by an invasive-diagnostic and interventional operator team or a single interventional operator. There is also research from China reporting that the use of anticoagulation (mainly LMWH) after primary PCI in patients with acute STEMI reduced mortality without increasing major bleeding. Other included research investigated the effect of omitting cardiac surgery, and treating just with antibiotics, in patients who had developed infective endocarditis after TAVI. We conclude this issue with research from Sweden reporting long-term outcomes associated with commonly used bioprosthetic aortic valves.

Thank you for the correspondence you have sent us – it is appreciated and we look forward to receiving more of your feedback.

Kind Regards,

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Percutaneous coronary intervention following diagnostic angiography by noninterventional versus interventional cardiologists

Authors: Lima FV et al.

Summary: These researchers analysed quarterly rates of *ad hoc* PCI cases from the US CathPCI Registry to compare those performed by an invasive-diagnostic and interventional operator team with those performed by a single interventional operator. For the 1,262,948 patients included, there was a decrease in the number of invasive-diagnostic operators and cases performed by invasive-diagnostic and interventional operator teams from ~9% to 5% over the Jan 2012 to March 2018 study period; patients treated by such teams were more often White and had fewer comorbidities than those treated by solo operators. There was considerable variation across the 1077 sites; >40% of sites had no procedures performed by an invasive-diagnostic and interventional operator team. Neither the risk of major adverse CV events nor the risk of net adverse CV events differed significantly between *ad hoc* PCIs performed by the teams versus the solo operators (respective adjusted ORs 1.04 [95% CI 0.97–1.11] and 0.98 [0.94–1.03]). Patients who underwent PCIs performed by the teams were more likely to undergo rarely appropriate PCI compared with those performed by solo operators (2.1% vs. 1.9%; OR 1.20 [95% CI 1.13–1.26]).

Comment: Historically, there has been a larger number of *ad hoc* PCIs performed by interventional cardiologists after a noninterventional cardiologist has performed a diagnostic angiogram. The current large-scale study from the US National Cardiovascular Data Registry CathPCI registry examined this practice and its impacts on outcomes. An interventional cardiologist was defined as having performed at least 25 PCIs during the study period, and in many sites (~40%) there were no cases performed by noninterventional cardiologists. Overall this practice has decreased, but after adjustment, there appeared to be similar patient outcomes with a significant reduction in inappropriate procedures, probably reflective of a different gatekeeper who may know the patient better. The study suggests that while it is an increasingly uncommon scenario (~5%), there appears to be no penalty in having a noninterventional cardiologist performing the diagnostic study and potentially some benefit in offering more detailed knowledge of the patient.

Reference: Circ Cardiovasc Interv 2022;15:e011086

Abstract

Clinical outcomes of percutaneous coronary intervention for chronic total occlusion in prior coronary artery bypass grafting patients

Authors: Shoaib A et al., British Cardiovascular Intervention Society (BCIS) and the National Institute for Cardiovascular Outcomes Research (NICOR)

Summary: Clinical characteristics and outcomes were compared between patients entered in a national UK database with stable angina who underwent CTO (chronic total occlusion) PCI in native arteries with (n=3233) versus without (n=16,848) prior CABG surgery. Patients who had undergone prior CABG were older, had more comorbidities and more had left ventricular systolic dysfunction. There was no significant difference between the group with versus without prior CABG for mortality during index hospital admission (adjusted OR 1.33 [CI 0.64–2.78]), at 30 days (1.28 [0.79–2.06]) or at 1 year (1.02 [0.87–1.29]), or for the likelihoods of in-hospital major adverse CV events (1.01 [0.69–1.49]), procedural complications (1.02 [0.88–1.18]), or requiring target-vessel revascularisation at 30 days (0.68 [0.40–1.16]) or 1 year (1.01 [0.83–1.22]); however, the prior CABG group had a lower procedural success rate (0.34 [0.31–0.39]).

Comment: CTOs are found in up to 20% of coronary angiograms and 22–26% are surgically revascularised. Over time, many of the grafts to these vessels fail, with few patients sent for redo-CABG, leaving medical therapy or PCI as the treatment of choice. This study reports the outcomes of stable angina patients treated with PCI between 2007 and 2014 using data from the large British Cardiovascular Intervention Society database, either with or without a prior history of CABG. Post-CABG patients were more complex and had a higher crude mortality rate at 30 days (0.8 vs. 0.43% [p=0.005]); however, after adjustments for baseline risk, outcomes were similar. The perforation rate was similar (1.42% vs. 1.51% [p=0.061]). This is a retrospective analysis without granular details of CTO complexity or whether attempts were on grafted or ungrafted vessels, but the results suggest that a history of CABG should not deter an attempt at PCI of a CTO if clinically indicated.

Reference: Catheter Cardiovasc Interv 2022;99:74–84
Abstract

Postprocedure anticoagulation in patients with acute ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention

Authors: Yan Y et al., CCC-ACS Investigators

Summary: Relationships between anticoagulation use following primary PCI and clinical outcomes were explored in 34,826 registrants from China with STEMI, of whom 75.4% received anticoagulation post-PCI. Compared with patients who did not receive postprocedural anticoagulation, those who did had a lower average age, were more stable at admission (lower bleeding risk score), and were more likely to have comorbidities, multivessel disease and have been treated ≤12 hours from symptom onset. Receipt of postprocedural anticoagulation (versus nonreceipt) significantly reduced the risk of in-hospital mortality (0.9% vs. 1.8%; adjusted HR 0.62 [95% CI 0.43–0.89]); postprocedural anticoagulation use was also associated with a trend for a lower risk of in-hospital major bleeding.

Comment: Patients undergoing primary PCI for STEMI receive intense antithrombotic therapy during the procedure, but generally parental anticoagulation is ceased at procedure end unless indicated for other reasons. The current collaborative study between the Chinese Society of Cardiology and the American Heart Association examined the implications of postprocedural anticoagulation in the absence of an existing indication. The vast majority of postprocedural anticoagulation used was LMWH (92%), and we are unsure as to the dose (therapeutic or prophylactic), start time and duration, which makes result interpretation difficult. Radial access was used in ~92% of cases and length of stay was 7–9 days, which seems long. In multivariable analysis, there seemed to be a predominantly non-CV mortality benefit of postprocedural anticoagulation without an increase in bleeding, which is not well explained. With more potent antiplatelets and reducing lengths of stay for STEMI patients, we may need more randomised trials if we are to change the way we use postprocedural anticoagulation.

Reference: JACC Cardiovasc Interv 2022;15:251–63
Abstract

Is routine postdilation during angiography-guided stent implantation as good as intravascular ultrasound guidance?

Authors: Lee Y-J et al.

Summary: These researchers pooled data from the IVUS-XPL and ULTIMATE RCTs of IVUS-guided versus angiography-guided DES implantation to compare IVUS-guided postdilatation in 1037 participants (1265 lesions) with angiography-guided postdilatation in 905 participants (1170 lesions), with 383 participants (397 lesions) who underwent angiography-guided DES implantation without postdilatation used as a reference group; all patients required stents that were ≥28mm in length. There was no significant difference between angiographic-guidance with versus without postdilatation for postintervention minimum lumen diameter (2.5 vs. 2.5mm [p=0.367]), but it was significantly greater for IVUS guidance with postdilatation versus angiographic guidance without postdilatation (2.6 vs. 2.5mm [p=0.046]) and for IVUS versus angiographic guidance with postdilatation (2.6 vs. 2.5mm [p<0.001]). The composite primary endpoint (cardiac-related death, target lesion-related MI or ischaemia-driven target lesion revascularisation at 3 years) was met by a lower proportion of the IVUS guidance with postdilatation group versus the angiography guidance with and without postdilatation groups (4.5% vs. 8.6% and 9.8%, respectively; HRs 0.51 [95% CI 0.35–0.74] and 0.44 [0.28–0.68]), with no significant difference between the angiography guidance with versus without postdilatation groups.

Comment: Traditionally stents are deployed using angiographic guidance, but two previous RCTs (IVUS-XPL and ULTIMATE) showed a clinical benefit of ultrasound guidance in long-lesion DES implantation. This study pooled these results to assess the benefits of postdilatation using angiographic or ultrasound guidance versus angiographically guided implantation without any postdilatation. IVUS-guided postdilatation resulted in a larger final balloon size and higher maximal pressure compared with angiographically-guided postdilatation. In contrast, there was no difference in these parameters between angiographic guidance with or without postdilatation. With respect to clinical endpoints, IVUS guidance was best. The finding that, where angiographic guidance alone was used, there appeared to be no benefit of postdilatation is intriguing. However, there were numerically less events in the postdilatation group, numbers where smaller and this was not randomised, so it would be premature to do away with postdilatation of stents.

Reference: Circ Cardiovasc Interv 2022;15:e011366
Abstract

Surgical treatment of patients with infective endocarditis after transcatheter aortic valve implantation

Authors: Mangner N et al.

Summary: Clinical characteristics and outcomes were reported for 111 patients who underwent cardiac surgery and also received antibiotics for TAVI-associated infective endocarditis, compared with 476 nonsurgical patients who only received antibiotics. There was no significant difference between patients who underwent cardiac surgery and those who only received antibiotics for in-hospital mortality or 1-year all-cause mortality, even after adjusting for selection and immortal time bias (adjusted HRs 0.92 [95% CI 0.80–1.05 and 0.95 [0.84–1.07]); similar results were seen when patients with and without TAVI prosthesis involvement were analysed separately. Factors that did predict in-hospital and 1-year all-cause mortality included logistic EuroSCORE I, *Staphylococcus aureus* infection, acute renal failure, persistent bacteraemia and septic shock.

Comment: There is a paucity of data on the long-term risks and management of infectious endocarditis occurring in patients with TAVI, with a reported incidence of 0.7–3.4% per patient per year. This international observational, multicentre registry attempts to fill some of the knowledge gaps. More than 44% of cases were a consequence of a healthcare-related infection, which leaves room for system improvements. The TAVI was involved with 60% of cases, and overall outcomes of these high risk patients was poor, with an in-hospital mortality of 31.9% and 1-year mortality of 47.9%. For those who survived initial hospitalisation, infectious endocarditis recurred in 12.2%. The authors report no significant survival benefit with surgery (only 19%) after adjusting for differences in baseline characteristics of those who were and were not operated on. There are a number of limitations, including whether exactly all cases were captured and the data were limited to centres that were part of the registry.

Reference: J Am Coll Cardiol 2022;79:772–85
Abstract

2-year outcomes after transcatheter versus surgical aortic valve replacement in low-risk patients

Authors: Forrest JK et al.

Summary: Two-year clinical and echocardiographic outcomes were reported for participants from the Evolut Low Risk Trial, which had randomised low surgical-risk patients with severe aortic stenosis to TAVR (n=730) or SAVR (n=684). The 2-year rates of death or disabling stroke (primary endpoint) in the respective TAVR and SAVR arms were 4.3% and 6.3% (p=0.084), which were comparable with the interim Bayesian rates (5.3% and 6.7%); there was also no significant difference for the endpoint's components of all-cause mortality (3.5% vs. 4.4% [p=0.366]) and disabling stroke (1.5% vs. 2.7% [p=0.119]) at 2 years. There was no convergence of the primary outcome curves between years 1 and 2.

Comment: The PARTNER 3 and Evolut Low Risk trials compared TAVR and SAVR in low surgical risk, and confirmed the benefits of TAVR in this population. The current paper presents the actual 2-year outcomes as opposed to the Bayesian statistical inference of the original Evolut Low Risk trial examining the self-expanding suprannular Evolut valve (Medtronic). This was a large scale multinational (including Australia), multicentre randomised trial. The noninferiority of Evolut was maintained at 2 years, with no convergence of the curves, with similar rates of clinical and nonclinical valve thrombosis (0.8% vs. 0.6%, TAVR versus SAVR). The Evolut valve had superior haemodynamic performance but a higher rate of new permanent pacemaker implantation (21.8% vs. 8.2%), and the long-term consequences of each of these parameters need to be seen. In this lower-risk population (mean age ~74 years), longer-term outcomes become more important, including future need for coronary access, which can be difficult with Evolut, but the results further inform multidisciplinary discussions with these patients.

Reference: J Am Coll Cardiol 2022;79:882–96
Abstract

Effect of wire jailing at side branch in 1-stent strategy for coronary bifurcation lesions

Authors: Choi Y-J et al.

Summary: This study of Korean registrants with bifurcation lesions who underwent a one-stent strategy using second-generation DESs for bifurcation PCI compared 819 who underwent side branch wire jailing prior to main vessel stenting and 1071 who did not. There was no significant difference between the wire jailing versus non-wire jailing groups for the incidence of final side-branch occlusion (1.8% vs. 2.9% [p=0.182]), but on multivariate analysis, wire jailing at the side branch did significantly protect against side branch occlusion after main vessel stenting and significantly lowered the incidence of side branch occlusion in patients with stenosis of ≥60% of the side branch (5.1% vs. 11.3%; OR 0.42 [95% CI 0.19–0.89]) or of the main vessel (3.1% vs. 6.2%; 0.49 [0.24–0.95]). After a median 52 months of follow-up, there was no significant difference between the wire jailing versus non-wire jailing group for target lesion failure (7.6% vs. 6.3% [p=0.343]).

Comment: When treating bifurcation lesions, the majority of operators will place a wire in significant side branches for protection during main branch stenting to help maintain flow and facilitate rewiring if needed. However, there is concern that the wire may become trapped or damaged. This study from the Korean Coronary Bifurcation Stenting Registry revealed jailing was used in 43% of cases, and side-branch occlusion occurred in 1.8% of patients with a jailed wire and 2.9% of those without. Whilst not statistically significant, in the true bifurcation subgroup, wire jailing was definitely protective. If abrupt side-branch occlusion occurred, the incidence of flow restoration was significantly higher in the jailed wire group. Importantly, the investigators found no cases of broken or trapped wires, suggesting no penalty in jailing wires. This retrospective study was not randomised and applies to a planned one-stent strategy, but is otherwise quite conclusive and can inform our practice. In particular we should protect the side branches if the angiographic stenosis is >60% at the origin of the side branches or in the main branch.

Reference: JACC Cardiovasc Interv 2022;15:443–55
Abstract

Drug-coated balloon for small coronary artery disease in patients with and without high-bleeding risk in the BASKET-SMALL 2 trial

Authors: Scheller B et al., for the BASKET-SMALL 2 Investigators

Summary: This prespecified subgroup trial analysis assessed the impact of bleeding risk in participants randomised to a DCB (n=382) or a second-generation DES (n=376) in patients with *de novo* lesions in coronary vessels suitable for PCI. Participants with a high risk of bleeding (n=155) were at increased risk of death within 3 years (HR 3.09 [95% CI 1.78–5.36]). There was a trend for a lower major bleeding event rate in the DCB versus DES group (1.6% vs. 3.7% [p=0.064]), although the rate was similar among participants at high bleeding risk (4.5% vs. 3.4%) while remaining lower in those who weren't (0.9% vs. 3.8%). Major adverse cardiac events did not differ between the DCB and DES groups for the subgroup at high bleeding risk or for the subgroup not at high bleeding risk (respective HRs 1.16 [95% CI 0.51–2.62] and 0.96 [0.62–1.49]).

Comment: Whilst guidelines recommend DAPT for 6 months in patients at low bleeding risk and 3 months for those at high bleeding risk, there is no distinction made between DESs or DCBs. There are little data to support a distinction, although consensus has been a shorter duration may be safe in DCB-treated patients with respect to ischaemic endpoints. This study is a prespecified secondary analysis of high bleeding risk patients (20% of cohort) enrolled in the multicentre, randomised controlled BASKET-SMALL 2 clinical trial, which compared the SeQuent Please paclitaxel-coated balloon (B Braun) with either a Xience (Abbott Vascular) or Taxus Element (Boston Scientific) DES. DAPT was recommended for 4 weeks in stable DCB patients and 6 months for DES patients, and for 12 months in acute coronary syndrome patients. Bleeding rates were lower in DCB patients, which did not come at a penalty of higher ischaemic events. Although an underpowered analysis, the results suggest a DCB strategy with shortened DAPT duration may be reasonable for patients at high bleeding risk undergoing PCI of *de novo* lesions in vessels <3mm.

Reference: Circ Cardiovasc Interv 2022;15:e011569
Abstract

Safety and feasibility of intravascular ultrasound guided zero-contrast percutaneous coronary intervention

Authors: Nandhakumar V et al.

Summary: Twenty seven patients at risk of contrast-induced acute kidney injury underwent zero-contrast PCI with IVUS guidance of 31 vessels in this prospective study. Technical success at the end of PCI (primary endpoint) was achieved for 87.1% of procedures, with a technical failure rate of 12.9%. There were no major adverse CV or cerebrovascular events recorded over 1 month of follow-up, at which time the median percent change in estimated GFR was –8.19% and no participant had required new initiation of renal replacement therapy.

Comment: Proven strategies to minimise contrast-induced acute kidney injury include prehydration and minimisation of contrast use to 2–3.7 times estimated GFR. The current prospective study from India used an aspirational goal of zero contrast. In brief, the diagnostic angiogram was uploaded and an ideal working view determined. Guiding catheter engagement was assessed fluoroscopically, observing guidewire tracking and checked with IVUS. Guidewires were placed in distal and proximal branches to create a metallic silhouette. After predilatation, IVUS was performed to mark proximal and distal landing zones in concert with fluoroscopy. After stenting, repeat IVUS ensured optimal stent deployment and ruled out uncovered dissection or geographical miss. A post-PCI echocardiogram checked for regional wall motion abnormalities and pericardial effusions. Notably, only 11% of patients screened (mostly due to complex anatomy) were enrolled in the study. Procedures took longer than average (89.70 minutes), only four patients needed any contrast and all procedures were completed safely. There was a case of guiding catheter thrombus, so they changed strategy to ensure regular catheter saline flushing. The paper articulates some good technical suggestions to help minimise contrast, even if we do not get down to zero contrast.

Reference: Int J Cardiol 2022;353:22–8
Abstract

Comparison of long-term performance of bioprosthetic aortic valves in Sweden from 2003 to 2018

Authors: Persson M et al.

Summary: Long-term re-intervention, all-cause mortality and HF hospitalisation rates associated with commonly used bioprosthetic aortic valves were explored in a Swedish population-based cohort of 16,983 adults who had undergone SAVR (with or without concomitant CABG or ascending aortic surgery). Deviations in clinical performance according to valve model (Perimount, Mosaic/Hancock, Biocor/Epic, Mitroflow/Crown, Soprano and Trifecta) were investigated. The lowest and highest 10-year cumulative re-intervention incidences were seen in the Perimount and Mitroflow/Crown valve model groups, respectively (3.6% and 12.2%); the Soprano valve model group had an estimated 10-year re-intervention incidence of 9.3%.

Comment: With the rise in TAVI procedures, there have been criticisms around lack of long-term valve durability data when compared with surgical bioprosthesis, even though there are limited such data on these surgical valves. The current study presents data from the Swedish Cardiac Surgery Registry, which captured all patients undergoing surgical bioprosthetic aortic valve replacement between 2003 and 2018. During a mean follow up of 7.1 years (max 16 years), 520 patients underwent re-intervention with SAVR or TAVR. The Perimount valve (Edwards) has a flexible cobalt-chromium alloy stent with three independent bovine pericardial leaflets and was the most commonly used valve model (66%), and its use increased during the study period. There were only 192 Trifecta valves implanted. The Perimount valve performed the best with respect to HF hospitalisation, re-intervention and mortality, and whilst this was not an RCT, it would appear to be the surgical valve that other iterations of SAVR and TAVR should be compared with.

Reference: JAMA Netw Open 2022;5:e220962
Abstract

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Independent commentary by 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.