Welcome to issue 23 of Interventional Cardiology Research Review.

The benefits of ultrasound guidance feature in two papers, one reporting its benefits for delivering thrombin injections as first-line therapy for uncomplicated iatrogenic femoral artery pseudoaneurysms, and the other for facilitating transradial arterial access. European research has reported that a second-generation zotarolimus-eluting stent with a fast-release profile combined with a short DAPT regimen tailored to the patient reduced the risk of major adverse CV events compared with a BMS in uncertain candidates for DES implantation, while another study found more major adverse CV events in patients with multivessel CAD who underwent PCI with an evorolimus-eluting stent compared with those who underwent CABG. This issue concludes with a study showing no difference in major bleeding outcomes between high-risk bivalirudin and UFH recipients undergoing transfemoral PCI.

I hope you enjoy reading about the selected research, and I look forward to your comments, questions and suggestions.

Kind Regards,

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Predictors of ventricular fibrillation at reperfusion in patients with acute ST-elevation myocardial infarction treated by primary percutaneous coronary intervention

Authors: Demidova MM et al.

Summary: Clinical predictors of reperfusion VF were identified in 3724 consecutive patients with STEMI treated with PCI, 71 of whom experienced reperfusion VF. Multivariate analyses revealed that the pre-PCI sum of ST-segment deviations in all leads of >1500μV independently predicted reperfusion VF (odds ratio 3.7 [95% CI 1.45, 9.41]), and despite a greater in-hospital mortality rate among patients with reperfusion VF versus those without (18.3% vs. 3.3% [p <0.001]), reperfusion VF was not an independent predictor of in-hospital death.

Comment: VF during reperfusion for STEMI is dramatic but occurs infrequently (1.5–3.1%). This single-centre retrospective study from Sweden looked at predictors of reperfusion VF. The occurrence of reperfusion VF was higher in inferior STEMIs in line with previous studies, and all patients had occluded infarct-related arteries at angiography, but the most powerful predictor was the sum of ST-segment elevation in affected leads. Interestingly, whilst such patients had a five times higher in-hospital mortality, this was most likely related to other patient factors rather than the reperfusion VF per se. The placement of defibrillator pads prophylactically should be considered for all STEMIs, but especially inferior STEMIs with large amounts of ST-segment elevation.


Abstract
Bifurcation lesions account for 15–20% of lesions treated by PCI. This

Reference: J Am Coll Cardiol 2015;65(6):533–43

Abstract

Difference for binary restenosis rates at 9 months’ follow-up (22.6% vs. 26.8% [p=0.44]). Periprocedural MI rate (13.6% vs. 10.1% [p=0.19]). The bifurcation stent group did have with the (nonsignificantly) higher rate in the bifurcation stent group due mainly to a higher endpoint of target vessel failure rate at 9 months (17.4% vs. 12.8% [p=0.42 for noninferiority]), between the bifurcation versus provisional stenting procedures was not seen for the primary summary:

Authors: Généreux P et al.

Summary: Patients with de novo true bifurcation lesions were randomly allocated to a dedicated bifurcation stent or main–vessel stent plus provisional stenting. Noninferiority between the bifurcation versus provisional stenting procedures was not seen for the primary endpoint of target vessel failure rate at 9 months (17.4% vs. 12.8% [p=0.42 for noninferiority]), with the (nonsignificantly) higher rate in the bifurcation stent group due mainly to a higher periprocedural MI rate (13.6% vs. 10.1% [p=0.19]). The bifurcation stent group did have a lower rate of side branch in-segment diameter stenosis among the angiographic cohort compared with the provisional group (31.6% vs. 38.6% [p=0.002]), with no between-group difference for binary restenosis rates at 9 months’ follow-up (22.6% vs. 26.8% [p=0.44]).

Comment: Bifurcation lesions account for 15–20% of lesions treated by PCI. This prospective, multicentre randomised controlled trial compared the current standard-of-care approach of provisional stenting with a dedicated non-DES bifurcation stent (Tryton). A core laboratory verified true bifurcation lesions in 88.1% of the entire cohort with the vast majority being left anterior descending/diagonal lesions (75.8%). The Tryton stent could not be deployed in 3.9% of cases, and overall these cases were longer and required more contrast than the standard approach. Whilst the results failed to show noninferiority of the dedicated bifurcation stent, it may have a place where the side branch is large or diffusely diseased, particularly if a DES version is produced. However for the moment, provisional stenting should remain the default approach.

Reference: J Am Coll Cardiol 2015;65(6):533–43

Abstract

A randomized trial of a dedicated bifurcation stent versus provisional stenting in the treatment of coronary bifurcation lesions

Authors: Chen DH et al.

Summary: This retrospective review of 121 consecutive patients assessed the efficacy and safety of first-line treatment for iatrogenic femoral artery pseudoaneurysms (mean maximum dimension 26.7mm; 25% multilobed) with ultrasound-guided injections of bovine thrombin 50–5000IU following cardiac diagnostic, interventional or catheter ablation procedures; 89% of the patients were receiving antiplatelet or anticoagulant therapy at the time of their injection. The primary success rate (immediate pseudoaneurysm thrombosis) was 92%, but was lower in multilobed versus unilobed iatrogenic femoral artery pseudoaneurysms (80% vs. 96% [p=0.016]). Outcomes were not significantly affected by use of antplatelets or anticoagulants or the size of the pseudoaneurysm. Seven patients experienced recurrence, including three who needed surgical repair, but there were no serious complications related to the injections.

Comment: Pseudoaneurysms are most commonly iatrogenic with an incidence ranging from around 1% after diagnostic angiography to 8% after PCI. This single-centre study from the Eastern Heart Clinic in Sydney examined 121 patients who underwent ultrasound-guided thrombin injection by an interventional cardiologist between 1999 and 2011. Primary success was excellent, with only three patients requiring surgical repair. A total of 89% of patients were on antplatelets or anticoagulants at the time of injection, and there were very few adverse reactions. The authors provide a comprehensive description of the procedure but, as this use is technically ‘off label’, there should be a full and frank discussion with the patients about the pros and cons of this approach.

Reference: Heart Lung Circ 2015;24(2):165–72

Abstract

Heart Failure Research Review


Cardiology Research Review

Real-time ultrasound guidance facilitates transradial access

Authors: Seto AH et al.

Summary: Patients undergoing transradial cardiac catheterisation were randomised to needle insertion with either palpation (n=351) or real-time ultrasound guidance (n=347) in the RAUST trial. Compared with palpation, ultrasound guidance was associated with a lower mean number of forward attempts required for access (1.65 vs. 3.05 [p<0.0001]), a greater first-pass success rate (64.8% vs. 43.9% [p<0.0001]), quicker time to access (88 vs. 108 sec [p=0.006]) and lower proportions of procedures needing ≥5 attempts (2.4% vs. 18.6% [p<0.001]) or lasting ≥5 min (3.7% vs. 6.8% [p=0.07]). There was no significant between-group difference for operator-reported spasms, postprocedure pain scores or bleeding complications.

Comment: The use of radial access for coronary interventional procedures is growing in popularity, but the radial artery is typically small and difficult to cannulate. As such, it is often compared with respective intervention of an arteriovenous coupler in addition to additional antihypertensive treatment or to maintain current treatment alone (control group). At 6 months, mean office and 24-hour systolic BPs had decreased by 26.9mm Hg and 13.5mm Hg, respectively, in the arteriovenous coupler group and 18.5mm Hg and 11.0mm Hg, respectively, in the control group. There was no significant between-group difference for the composite safety endpoint of death, MI or stroke, but PCI was associated with higher rates of any repeat revascularisation and spontaneous MI.


Central arteriovenous anastomosis for the treatment of patients with uncontrolled hypertension (the ROX CONTROL HTN study)

Authors: Lobo MD et al., for the ROX CONTROL HTN Investigators

Summary: Patients with baseline office systolic BP ≥140mm Hg and average daytime ambulatory BP ≥135/85mm Hg despite antihypertensive treatment (n=93) were randomised to undergo implantation of an arteriovenous anastomosis. This multicentre, international study presents the average number of events were related to stent thrombosis. This study, which used second-generation DESs, was designed to enrol 1800 patients but due to slow recruitment was terminated early. Stable angina was the presenting symptom in ~47% of patients, ~40% had a history of diabetes and the mean SYNTAX score was 24 consistent with intermediate complexity of disease. Despite the known superiority of these newer stents when compared with first-generation DESs, PCI was not noninferior to surgery and at longer term follow-up was in fact inferior, mainly due to an increased need for repeat revascularisation in the stenting arm.


Zotarolimus-eluting versus bare-metal stents in uncertain drug-eluting stent candidates

Authors: Valgimigli M et al.

Summary: These researchers randomised 1606 uncertain DES candidates with stable or unstable symptoms to receive a zotarolimus-eluting stent or a BMS. The median duration of DAPT, which was determined by patient characteristics rather than stent characteristics and allowed for a personalised 1-month regimen, was 32 days (range 30–180), and did not differ between groups. Compared with BMS recipients, a lower proportion of zotarolimus-eluting stent recipients experienced a primary endpoint event over 1 year (major adverse CV event [including death], MI or TVR: 17.5% vs. 22.1%; HR 0.76 [95% CI 0.61, 0.95]), due to fewer MIs (2.9% vs. 8.1% [p<0.001]) and TVRs (5.9% vs. 10.7% [p=0.001]), and their definite/probable stent thrombosis rate was also lower (2.0% vs. 4.1%; [p=0.019]).

Comment: DESs consistently reduce the risk of restenosis when compared with BMSs. However, due to concerns about late stent thrombosis, 12 months of DAPT is recommended, which may increase bleeding. This novel randomised, single-blinded trial compared the Endeavour® zotarolimus-eluting stent with a BMS in patients who had uncertain indications for a DES. The reasons for uncertain indication included high risk of bleeding in 50% (age >80 years, recent bleeding, on anticoagulants, etc) and high thrombotic risk in ~18% (need for surgery, intolerant of antiplatelets, etc). Despite a median duration of DAPT of 32 days, the zotarolimus-eluting stent performed better than the BMS, which may be attributable to the unique biocompatible polymer coating and rapid elution kinetics of this particular stent.

Reference: J Am Coll Cardiol 2015;65(8):805–15

Randomized trial of primary PCI with or without routine manual thrombectomy

Authors: Jolly SS et al., for the TOTAL Investigators

Summary: In this study, 10,732 patients with STEMI undergoing primary PCI were randomised to a strategy of routine upfront manual thrombectomy or to PCI alone. The primary outcome (composite of death from CV causes, recurrent MI, cardiogenic shock or NYHA class IV HF within 180 days) occurred in 6.9% of the thrombectomy group and 7.0% of the PCI only group (p=0.86); the respective rates of CV death (3.1% and 3.5% [p=0.34]) and of the primary outcome plus stent thrombosis or TVR (9.9% and 9.8% [p=0.95]) were also similar. Routine manual thrombectomy was associated with a higher 30-day stroke rate than PCI alone (0.7% vs 0.3%; HR 2.06 [95% CI 1.13, 3.75]).

Comment: The TAPAS single-centre study suggested that routine aspiration thrombectomy during primary PCI reduced mortality when compared with simple angioplasty and stenting. Subsequently, the large multicentre TASTE trial showed no reduction in mortality, casting doubt about the guidelines. The current trial, the largest so far, should be the last word on the need for routine aspiration thrombectomy, showing it was not superior to a strategy of PCI alone with bailout thrombectomy if required (used in 71% of patients in this trial). Because of the signal of increased risk of stroke in the aspiration arm, operators using thrombectomy should ensure the guiding catheter is repositioned in the coronary ostium during removal of the thrombectomy catheter, and the guiding catheter should be aspirated to ensure removal of air and thrombus prior to subsequent injections to reduce the risk of embolisation.

Randomized trial of complete versus lesion-only revascularization in patients undergoing primary percutaneous coronary intervention for STEMI and multivessel disease

Authors: Gerstchik AH et al.

Summary: The CvLPRIT trial randomised 296 patients presenting for primary PCI with multivessel disease to in-hospital complete revascularisation (n=148) or revascularisation of only the infarct-related artery (n=148); randomisation was stratified by infarct location and symptom onset. Primary endpoint events (all-cause death, recurrent MI, HF and ischaemia-driven revascularisation within 12 months) occurred in a lower proportion of patients who underwent complete revascularisation versus revascularisation of the infarct-related artery only (10.0% vs. 21.2%; HR 0.45 [95% CI 0.24, 0.84]), with a trend for a benefit seen at 30 days (p=0.055); nonsignificant reductions were seen for all the primary endpoint components. There were no significant between-group differences for ischaemic burden or safety endpoints (major bleeding, contrast-induced nephropathy or stroke).

Comment: The PRAMI trial cast doubt on the previous mantra that we should only treat the infarct-related artery in STEMI and leave nonculprit lesions alone. This smaller study confirmed that complete revascularisation reduced the primary endpoint when compared with culprit only PCI. Notable differences to PRAMI included the composite endpoint and the ability to defer nonculprit PCI in the intervention arm to later in the hospital stay (36% in this study). Larger ongoing trials will provide a more definitive answer; however, in the interim clinicians should use clinical judgement weighing up the haemodynamic status of the patient, lesion complexity, renal function and even time of day to determine whether to treat all lesions up front or to stage nonculprit PCI during the same hospitalisation or after discharge.

Reference: J Am Coll Cardiol 2015;65(10):963–72

Novel Approaches for Preventing or Limiting Events (Naples) III trial: randomized comparison of bivalirudin versus unfractionated heparin in patients at increased risk of bleeding undergoing transfemoral elective coronary stenting

Authors: Briguior C et al.

Summary: Consecutive biomarker-negative patients scheduled for PCI via the femoral approach who had an elevated bleeding risk were randomised to receive UFH (unfractionated heparin; n=419) or bivalirudin (n=418). No significant difference was seen between the UFH versus bivalirudin recipients for in-hospital major bleeding (primary endpoint; 2.6% vs. 3.3%; odds ratio 0.78 [95% CI 0.35, 1.72]) or distribution of access-site and nonaccess-site bleeding (18% and 82% vs. 50% and 50%, respectively [p=0.10]).

Comment: There has been much debate about whether bivalirudin is superior to UFH in STEMI and leave nonculprit lesions alone. This smaller study confirmed that complete revascularisation reduced the primary endpoint when compared with culprit only PCI. Notable differences to PRAMI included the composite endpoint and the ability to defer nonculprit PCI in the intervention arm to later in the hospital stay (36% in this study). Larger ongoing trials will provide a more definitive answer; however, in the interim clinicians should use clinical judgement weighing up the haemodynamic status of the patient, lesion complexity, renal function and even time of day to determine whether to treat all lesions up front or to stage nonculprit PCI during the same hospitalisation or after discharge.