

Cardiology

RESEARCH REVIEW™

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Issue 84 – 2020

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Abbreviations used in this issue

AF = atrial fibrillation
CABG = coronary artery bypass grafting
CTCA = computed tomography coronary angiography
ECG = electrocardiography
HR = hazard ratio
MI = myocardial infarction
NOAC = non-vitamin K oral anticoagulant
NSTEMI = non ST-elevation MI
NT-proBNP = N-terminal pro-B-type natriuretic peptide
PCI = percutaneous coronary intervention
STEMI = ST-elevation MI
TAVI = transcatheter aortic valve implantation

Welcome to the latest issue of Cardiology Research Review.

In this issue, the GALILEO investigators report that NOACs are not the best form of anticoagulation after TAVI, Australian researchers find that abstinence from alcohol reduces the recurrence of arrhythmias in regular drinkers with AF, and a French randomised controlled trial shows that daily low-dose colchicine reduces the risk of ischaemic cardiovascular events after a recent MI. The ERADICATE-AF trial reports the benefits of catheter ablation in conjunction with renal denervation in patients with hypertension and paroxysmal AF, and Australian researchers find that ascending aortic dilatation with abnormal anterior effacement is common in retired elite rugby players.

We hope you enjoy these and the other selected studies, and look forward to any feedback you might have.

Kind regards,

Professor Alexander Sasse

alexandersasse@researchreview.co.nz

A controlled trial of rivaroxaban after transcatheter aortic-valve replacement

Authors: Dangas GD et al., for the GALILEO Investigators

Summary: The GALILEO trial investigated the effects of rivaroxaban on thromboembolic events after TAVI. After undergoing successful TAVI, 1644 patients without an established indication for oral anticoagulation were randomised to receive rivaroxaban 10 mg/day (+ aspirin 75–100 mg/day for the first 3 months) or aspirin 75–100 mg/day (+ clopidogrel 75 mg/day for the first 3 months; antiplatelet group). During a median 17 months of follow-up, 105 patients in the rivaroxaban group and 78 in the antiplatelet group died or had a first thromboembolic event (HR, 1.35; 95% CI 1.01–1.81; $p=0.04$). Major, disabling, or life-threatening bleeding occurred in 46 and 31 patients in the respective groups (HR, 1.50; 95% CI 0.95–2.37; $p=0.08$), and 64 and 38 patients, respectively, died (HR, 1.69; 95% CI 1.13–2.53).

Comment: Following TAVI the most appropriate form of anticoagulation treatment remains unclear. This randomised trial compared 10mg rivaroxaban (first 3 months with aspirin) to aspirin (first 3 months with clopidogrel); median follow up was 17 months during which time patients who developed AF were changed to guideline-directed therapy. Regarding the primary outcome of death or embolic complications, patients in the rivaroxaban group had more events (HR, 1.35; 95% CI 1.01–1.81; $p=0.04$). Concerningly, the mortality rate was also higher in the rivaroxaban group. At least this seems to clearly indicate that NOACs might not be the right form of anticoagulation post TAVI.

Reference: *N Engl J Med* 2020;382:120-9

[Abstract](#)

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Independent commentary by Professor Alexander Sasse

Professor Alexander Sasse is Consultant Cardiologist and Clinical Director of the Cardiology Department at Wellington Hospital/CCDHB. His clinical interests include the various modalities of cardiac imaging, structural heart disease and intervention, general cardiology and the prevention of stroke. **For full bio [CLICK HERE](#).**



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Alcohol abstinence in drinkers with atrial fibrillation

Authors: Voskoboinik A et al.

Summary: This Australian study investigated the effect of abstinence from alcohol on AF recurrence and burden in drinkers with AF. 140 adults who consumed ≥ 10 standard drinks per week and who had paroxysmal or persistent AF in sinus rhythm at baseline were randomised to either abstain from alcohol or continue their usual alcohol consumption. After a 2-week blanking period, the abstinence group had a longer period before recurrence of AF than the control group (HR, 0.55; 95% CI 0.36–0.84; $p=0.005$); AF recurred in 53% and 73% of patients in the respective groups. AF burden over 6 months of follow-up was lower in the abstinence group than in the control group (median percentage time in AF: 0.5% vs 1.2%; $p=0.01$).

Comment: This Australian study randomised paroxysmal AF patients that were already drinking alcohol into an abstinent group and a control group (obviously non-blinded). Abstinence here means a reduction by about 90%, duration was 6 months, and an alcohol diary was kept. Monitoring was through pacemaker, loop recorder or phone-based ECG monitors. Recurrence of $>30s$ AF was recorded in 53% of abstinent compared to 73% of control patients (primary end-point). AF burden was also lower in the abstinent group. The authors attributed this outcome to multiple factors, including a direct alcohol effect, weight loss and others. Cheers.

Reference: *N Engl J Med* 2020;**382**:20-8

[Abstract](#)

Efficacy and safety of low-dose colchicine after myocardial infarction

Authors: Tardif J-C et al.

Summary: This study investigated the efficacy and safety of low-dose colchicine after MI. 4745 patients were recruited within 30 days of an MI and randomised to receive either low-dose colchicine (0.5 mg/day) or placebo. During a median follow-up of 22.6 months, the primary efficacy end-point (a composite of death from cardiovascular causes, resuscitated cardiac arrest, MI, stroke, or urgent hospitalisation for angina leading to coronary revascularisation) occurred in 5.5% of patients in the colchicine group compared with 7.1% in the placebo group (HR, 0.77; 95% CI 0.61–0.96; $p=0.02$). The incidence of diarrhoea did not differ significantly between groups.

Comment: Colchicine is currently indicated for the treatment of pericarditis, but is the anti-inflammatory effect relevant after an MI? This French randomised trial enrolled patients up to 30 days following an MI and compared low-dose colchicine (0.5mg) to placebo. 4745 patients were enrolled; median follow up was 23 months. The clinical primary end-point occurred in 5.5% of patients in the colchicine group compared to 7.1% in the control group. This was mostly driven by fewer strokes but in particular fewer hospitalisations. Death, myocardial reinfarction and cardiac arrests were not different. Is this an old drug with a new indication?

Reference: *N Engl J Med* 2019;**381**:2497-2505

[Abstract](#)

Effect of renal denervation and catheter ablation vs catheter ablation alone on atrial fibrillation recurrence among patients with paroxysmal atrial fibrillation and hypertension

Authors: Steinberg JS et al.

Summary: The ERADICATE-AF trial investigated the efficacy of catheter ablation combined with renal denervation in patients with hypertension and paroxysmal AF. 302 patients with hypertension (despite taking ≥ 1 antihypertensive medication), paroxysmal AF, and plans for ablation were randomised to undergo catheter ablation alone or in conjunction with renal denervation. Freedom from AF, flutter, or tachycardia at 12 months (primary end-point) was observed in 56.5% of patients undergoing catheter ablation alone and 72.1% of those undergoing catheter ablation + renal denervation (HR, 0.57; 95% CI 0.38–0.85; $p=0.006$). From baseline to 12 months, mean systolic blood pressure decreased from 151mm Hg to 147mm Hg in the catheter ablation-only group, and from 150mm Hg to 135mm Hg in the catheter ablation + renal denervation group (between-group difference, -13mm Hg; 95% CI -15 to -11mm Hg; $p<0.001$). Procedural complications occurred in 4.7% and 4.5% of patients in the respective groups.

Comment: Renal denervation and ablation of AF (what a combination!) compared to AF ablation alone. A multicentre, single-blind study in 302 hypertensive patients. Ablating renal efferent sympathetic nerves was hypothesised to lower systemic sympathetic tone. The primary end-point of freedom from $>30s$ AF at 12 months was observed in 57% of the ablation-only group compared to 72% in the ablation + renal denervation group ($p=0.006$). Blood pressure reduction was more pronounced in the renal denervation group, although there were a number of limitations to this result. Renal ablation keeps coming back; this is a thought-provoking outcome.

Reference: *JAMA* 2020;323(3):248-55

[Abstract](#)



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Cardiology Research Review

Percutaneous coronary angioplasty versus coronary artery bypass grafting in the treatment of unprotected left main stenosis

Authors: Holm NR et al., for the NOBLE Investigators

Summary: This report presented 5-year outcomes of the NOBLE trial that compared PCI and CABG for unprotected left main stenosis. In the trial, 1201 patients with left main coronary artery disease requiring revascularisation were randomised to receive PCI or CABG at 36 hospitals in 9 northern European countries. The primary end-point was major adverse cardiac or cerebrovascular events (MACCE; a composite of all-cause mortality, non-procedural MI, repeat revascularisation, and stroke). Kaplan-Meier 5-year estimates of MACCE were 28% for PCI and 19% for CABG (HR, 1.58; 95% CI 1.24–2.01). All-cause mortality occurred in 9% of patients in each group ($p=NS$), non-procedural MI occurred in 8% of PCI and 3% of CABG recipients (HR, 2.99; 95% CI 1.66–5.39; $p=0.0002$), and repeat revascularisation was needed in 17% and 10% of patients in the respective groups (HR, 1.73; 95% CI 1.25–2.40; $p=0.0009$).

Comment: Paper 1 on left main stem disease treatment, a formal randomised trial comparing PCI in selected patients to CABG. This was a follow-up after 5 years, a predefined end-point to achieve the estimated statistical power. The primary MACCE-driven end-point occurred in 28% of PCI compared to 19% of CABG patients. This exceeded the limit for non-inferiority, demonstrating that CABG was superior to PCI ($p=0.0002$). While all-cause mortality was not different, most other end-points favoured CABG. The authors suggested limiting PCI to selected patients and "optimising PCI".

Reference: *Lancet* 2020;395(10219):191-9

[Abstract](#)

Percutaneous coronary intervention for left main coronary disease in New Zealand: National linkage study of characteristics and in-hospital outcomes (ANZACS-QI 38)

Authors: Wang TKM et al.

Summary: This study reviewed outcomes after PCI for left main stem (LMS) coronary disease in NZ. Data for all patients undergoing PCI for LMS disease from 1st September 2014 until 24th September 2017 were extracted from the All New Zealand Acute Coronary Syndrome-Quality Improvement (ANZACS-QI) registry. The cohort comprised 469 patients (mean age 70.8 years, 71% male, 72% unprotected LMS). Indications for PCI included STEMI (18%) and NSTEMI or unstable angina (49%). Patients with unprotected LMS were more likely to present with an acute coronary syndrome (73% vs 48%; $p<0.001$) and to die in hospital (9.4% vs 3.9%; $p=0.045$) than patients with protected LMS. In-hospital mortality after acute STEMI PCI was higher than that for other indications in patients with unprotected LMS (21.1% vs 6.1%; $p<0.001$). STEMI, femoral access and worse renal function were independent predictors of in-hospital death and major adverse cardiovascular events.

Comment: Paper 2 on LMS treatment: real world local data from the ANZACS-QI registry. Over 3 years there were 469 LMS interventions, 339 of them unprotected. Unlike the randomised NOBLE trial, this was a high-risk cohort. Observed mortality was significantly higher than trial patients (6.1% vs 0.3% in NOBLE). Strong predictors for non-procedure-related adverse outcome were renal impairment and acute presentation. The authors commented on the relatively low rate of adjunct intracoronary imaging. Importantly, this paper puts current practice into perspective; randomised trial data mostly apply to the selected subgroup and are best not generalised.

Reference: *Cardiovasc Revasc Med* 2019; published online Aug 23

[Abstract](#)

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Shift work and the risk of coronary artery disease

Authors: Havakuk O et al.

Summary: This study investigated whether shift workers are prone to a higher burden of coronary artery disease (CAD) than non-shift workers. 349 adults who had undergone a CTCA were questioned about their routine work schedule prior to the CCTA test. From the cohort, 89 shift workers were propensity score-matched with 89 non-shift workers. Analysis of the pairs showed that shift workers had a higher prevalence of CAD than non-shift workers (74.2% vs 53.9%; $p=0.01$), and a lower prevalence of coronary calcium scores of zero (46.8% vs 63.4%; $p=0.034$). Stenosis $>50\%$ was more prevalent in shift workers (20.2% vs 11.2%; $p=0.006$), as was the extent of CAD (25.8% vs 13.5% of patients had ≥ 1 -vessel disease; $p=0.06$).

Comment: This group in Israel examined work patterns in 349 patients that had undergone a CTCA. 27% of them had worked in shifts, over a duration of 10.3 ± 6.1 years. While the raw data did not show much difference, once patients were propensity matched the differences became more apparent. CAD was present in 74% of shift workers compared to 54% of controls (odds ratio, 2.4; 95% CI 1.2–5; $p=0.01$). Extensive CAD was also more prevalent in shift workers. While there might be other lifestyle factors associated with shift work, the authors' impression was that by matching the patients the shift work as such appears to be an independent contributor.

Reference: *Cardiology* 2018;139:11-16

[Abstract](#)

Rugby player's aorta: Alarming prevalence of ascending aortic dilatation and effacement in elite rugby players

Authors: Kay S et al.

Summary: This Australian study evaluated the prevalence and severity of ascending aortic dilatation in elite rugby players. 152 asymptomatic players aged 21–65 (mean 45) years with a history of at least 5 years of high level competitive rugby underwent transthoracic echocardiography. Z-scores (compared with a population mean) were calculated for aortic root and ascending aortic size. 24% of players had a z-score >2 for aortic root size (compared with an expected prevalence of 2.3%; $p<0.001$) and 4% had a z-score >3 (compared with an expected prevalence of 0.1%; $p<0.001$). 62 players (41%) had an aortic root >40 mm in diameter. 53% of players had a z-score >2 for ascending aortic size and 22% had a z-score >3 . 88 players (58%) had abnormal anterior aortic effacement at the sinotubular junction. Abnormal aortic dilatation was associated with a longer duration of competitive rugby participation, and effacement was associated with elite status.

Comment: Triggered by an unusual appearing aorta in a professional rugby player, this Australian study analysed the aortas of 152 competitive rugby players via echocardiography. Most were retired and the average age was 45 years. 41% had an aortic root greater than 40mm. Measurements were compared to a reference dataset, adjusting for body size and age. With that adjustment, 4% had a z-score >3 , compared to 0.1% in the general population. No increased number of aortic dissection was demonstrated in the analysed population. The authors concluded that this finding warrants further studies and suggested initiation of screening tests.

Reference: *Heart Lung Circ* 2020;29(2):196-201

[Abstract](#)

Balloon-expandable versus self-expanding transcatheter aortic valve replacement

Authors: van Belle E et al.

Summary: This analysis of data from the FRANCE-TAVI Registry compared outcomes after balloon-expandable (BE) versus self-expanding (SE) transcatheter heart valve implantation. 3910 patients treated with BE-TAVI in France in 2013–2015 were propensity score-matched with 3910 patients treated with SE-TAVI during the same time. The first coprimary outcome was at least moderate paravalvular regurgitation or in-hospital mortality, or both. The second coprimary outcome was 2-year all-cause mortality. The incidence of the first coprimary outcome was higher with SE-TAVI than with BE-TAVI (19.8% vs 11.9%; relative risk, 1.68; 95% CI 1.46–1.91; $p<0.0001$). During follow up, 2-year mortality rates were higher in SE-TAVI patients (29.8% vs 26.6%; HR, 1.17; 95% CI 1.06–1.29; $p=0.003$).

Comment: TAVI is done on two major technical platforms, SE and BE. Now that the general indications of TAVI are established, the question of technology supremacy has been asked. The published data are from the French national registry and to allow comparison the datasets were propensity matched. The lower number of SE meant that those patients were matched, dropping a number of BE patients from the analysis. Outcomes focussed on paravalvular leaks and mortality. SE-TAVI compared unfavourably to BE-TAVI in all major parameters. Like in so many other areas of cardiology, randomised comparison trials are required to further characterise these findings.

Reference: *Circulation* 2020;141(4):243-59

[Abstract](#)



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Preoperative N-terminal pro-B-type natriuretic peptide and cardiovascular events after noncardiac surgery

Authors: Duceppe E et al.

Summary: This cohort study investigated whether preoperative NT-proBNP levels are predictive of vascular death and myocardial injury after non-cardiac surgery. 10,402 patients aged ≥ 45 years who were undergoing inpatient non-cardiac surgery at 16 hospitals in 9 countries had NT-proBNP levels measured before surgery and troponin T levels measured daily for up to 3 days after surgery. In multivariable analyses, compared with preoperative NT-proBNP values <100 pg/ml (reference group), levels of 100 to <200 pg/ml, 200 to <1500 pg/ml, and ≥ 1500 pg/ml were associated with adjusted HRs of 2.27 (95% CI 1.90–2.70), 3.63 (95% CI 3.13–4.21), and 5.82 (95% CI 4.81–7.05) for the composite end-point of vascular death and myocardial injury within 30 days after surgery. Corresponding incidences of the primary composite outcome were 12.3%, 20.8%, and 37.5%, respectively. Adding NT-proBNP thresholds to clinical stratification resulted in a net absolute reclassification improvement for 258 out of every 1000 patients.

Comment: This international, prospective trial of over 10,000 patients investigated the ability of NT-proBNP levels to predict outcomes from patients undergoing non-cardiac surgery. Cut-offs of 100/200/1500 pg/ml were chosen, with <100 pg/ml as the reference group. Primary end-points were vascular death or myocardial injury. The results clearly demonstrated a correlation, with HRs for the 3 abnormal NT-proBNP groups of 2.3, 3.6 and 5.8, respectively. Beyond the primary end-point, NT-proBNP also predicted all-cause mortality. Quite convincing results to implement in select patients.

Reference: *Ann Intern Med* 2020;172(2):96-104

[Abstract](#)

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