

# Cardiology Research Review™

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Issue 155 - 2023

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## Abbreviations used in this issue:

AF = atrial fibrillation; CAD = coronary artery disease;  
CHD = coronary heart disease; CRT = cardiac resynchronisation therapy;  
DOAC = direct oral anticoagulant; ECG = electrocardiography;  
HF = heart failure; HFREF = HF with reduced ejection fraction;  
HR = hazard ratio; LVEF = left ventricular ejection fraction;  
MI = myocardial infarction; PCSK9 = proprotein convertase subtilisin/kexin type 9.

## Welcome to the latest issue of Cardiology Research Review.

In this issue, two studies report the use of percutaneous transcatheter edge-to-edge repair for mitral or tricuspid regurgitation, evidence suggests that the coronary artery calcium score is a better predictor of cardiovascular events than the older risk scores, and the results of a US study suggest that we need to improve the quality of DOAC use and dosing in patients with AF.

We hope you find these and the other selected studies interesting, and welcome your feedback.

Kind Regards,

Associate Professor John Amerena

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## Five-year follow-up after transcatheter repair of secondary mitral regurgitation

**Authors:** Stone GW et al., for the COAPT Investigators

**Summary:** This 5-year follow-up of the COAPT trial investigated outcomes after transcatheter repair of severe mitral regurgitation compared with guideline-directed medical therapy (GDMT). 614 patients with HF and moderate-to-severe or severe secondary mitral regurgitation who were symptomatic despite taking maximal doses of GDMT were randomised to undergo transcatheter edge-to-edge repair plus receive GDMT (device group) or to receive GDMT alone (controls) at 78 sites in the US and Canada. The annualised rate of HF hospitalisations during 5 years of follow-up was lower in the device group than the control group (33.1% vs 57.2% per year; HR 0.53, 95% CI 0.41–0.68). Five-year all-cause mortality was also lower in the device group (57.3% vs 67.2%; HR 0.72, 95% CI 0.58–0.89), as was 5-year death or HF hospitalisation (73.6% vs 91.5%; HR 0.53, 95% CI 0.44–0.64). Device-specific safety events occurred in 1.4% of patients, with all events reported within 30 days after the procedure.

**Comment:** There are many patients with HF and moderate-to-severe mitral regurgitation who remain symptomatic despite optimal medical therapy. Surgery is a major undertaking in these patients who are usually elderly with comorbidities. This paper describes the longer-term follow up of the COAPT study, which looked at percutaneous transcatheter edge-to-edge repair of mitral regurgitation in patients with HF, and showed that the benefits seen in the original study at 2 years were durable out to 5 years. Thus, MitraClip™ should be considered in patients with HF and mitral regurgitation who are poor surgical candidates, but unfortunately this procedure is not widely available in Australia.

**Reference:** *N Engl J Med* 2023;388(22):2037-48

[Abstract](#)

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ACS, acute coronary syndrome; PBS, Pharmaceutical Benefits Scheme.

**References:** 1. Pharmaceutical Benefits Scheme, Drug Utilisation Sub-Committee. Ticagrelor: analysis of predicted versus actual utilisation, Public Release Document. February 2016. Available at <https://www.pbs.gov.au/industry/listing/participants/public-release-docs/2016-02/ticagrelor-dusc-prd-2016-02.pdf>. Accessed July 2022.

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## Transcatheter repair for patients with tricuspid regurgitation

**Authors:** Sorajja P et al., for the TRILUMINATE Pivotal Investigators

**Summary:** This randomised controlled trial investigated the use of percutaneous tricuspid transcatheter edge-to-edge repair for patients with severe tricuspid regurgitation. 350 patients (mean 78 years, 54.9% female) with symptomatic severe tricuspid regurgitation were enrolled at 65 centres in the US, Canada, and Europe and were randomised 1:1 to receive either percutaneous tricuspid transcatheter edge-to-edge repair or medical therapy (controls). During the 1-year follow-up, the incidence of death or tricuspid valve surgery and the rate of HF hospitalisations did not differ significantly between groups, but quality of life (measured by the Kansas City Cardiomyopathy Questionnaire) improved significantly in the transcatheter repair group compared with controls ( $p < 0.001$ ).

**Comment:** Symptomatic severe tricuspid regurgitation is very common in patients with heart and lung disease, and at present symptomatic treatment or surgery is all we have to offer. Standalone surgery on the tricuspid valve is seldom performed due to high morbidity and mortality, and even when patients are having open heart procedures, repair or replacement of the tricuspid valve is seldom performed. Percutaneous tricuspid transcatheter edge-to-edge repair, similar to the MitraClip™ procedure in the previous study, seems to be safe and improves patient symptoms and quality of life, but this study showed no impact on hospitalisation, transition to surgery or death, so it is unlikely to be widely used unless subsequent studies show improvement in hard end-points.

**Reference:** *N Engl J Med* 2023;388:1833-42

[Abstract](#)

## Coronary artery calcium score and polygenic risk score for the prediction of coronary heart disease events

**Authors:** Khan SS et al.

**Summary:** This study investigated the use of coronary artery calcium score (CCS) and/or polygenic risk score for the prediction of CHD risk when added to a traditional risk factor-based model. Data for 1991 participants from the MESA study and 1217 from the Rotterdam study who were aged 45–79 years and were free of clinical CHD at baseline were analysed. Both CCS and polygenic risk score were significantly associated with 10-year risk of incident CHD in MESA (C statistic = 0.76 for CCS and 0.69 for the polygenic risk score). Overall categorical net reclassification improvement was significant when CCS was added to the traditional risk factor-based score, but was not significant when the polygenic risk score was added to the traditional risk factor-based score. Similar findings were observed for 10-year risk in Rotterdam study participants.

**Comment:** The new Australian cardiovascular risk calculator has just been released and includes CCS as one of its components. This study shows that CCS is a better predictor of cardiovascular events than the older risk scores, so it adds valuable information in risk prediction. Unfortunately, CCS is not funded in Australia, and there is a considerable out-of-pocket expense, so it is not as widely used as it should be. This information should support the case for reimbursement, but in the current economic circumstances I don't think it is likely in the near term.

**Reference:** *JAMA* 2023;329(20):1768-77

[Abstract](#)



## Cardiology Research Review™

### Independent commentary by Associate Professor John Amerena

Associate Professor John Amerena trained in Melbourne before spending four years in the United States at the University of Michigan. Over that period of time he worked in the fields of hypertension and hyperlipidemia, before returning to Australia where he is now a Cardiologist at Barwon Health. He currently has a joint appointment in the Department of Clinical and Biomedical Sciences at the University of Melbourne and the Department of Epidemiology and Preventive Medicine at Monash University. He is the director of the Geelong Cardiology Research Unit, which is currently involved in many phase II-III clinical trials. While still actively researching in hypertension, his focus has changed to research in antithrombotic/antiplatelet therapies, particularly in the context of acute coronary syndromes and atrial fibrillation. Heart failure is also a major interest, and he is also the Director of the Heart Failure Programme at Barwon Health. He is well published in these areas, as well as in many other areas of cardiovascular medicine.

## Analysis of oral anticoagulant dosing and adherence to therapy among patients with nonvalvular atrial fibrillation

**Authors:** Rymmer JA et al.

**Summary:** This retrospective US study evaluated oral anticoagulant dosing and adherence to therapy among patients with nonvalvular AF. Data from the Symphony Health claims data set were analysed for 86,919 patients with  $CHA_2DS_2VASc$  scores  $\geq 2$  who received a DOAC between Jan 2015 and Dec 2017. A total of 7335 (8.4%) patients were found to have received an appropriately reduced dose, and 10,964 (12.6%) received an underdose not consistent with FDA recommendations. Therefore, 59.9% of patients who received a reduced dose received an inappropriate dose. Patients who received off-label lower doses of DOACs were older and had a higher  $CHA_2DS_2VASc$  score than those who received appropriate doses. Renal dysfunction, age, HF, and the prescribing clinician being in a surgical specialty were associated with dosing not recommended by FDA labelling. 31.9% of patients with creatinine clearance  $< 60$  ml/min who were taking DOACs were either underdosed or excess-dosed. Underdosing with DOACs was associated with a lower likelihood of DOAC adherence and higher risk of discontinuation by 1 year.

**Comment:** This study from the Duke Research Institute shows that many patients in the US are prescribed inappropriately low dose DOACs. This pattern is seen globally and the patients who are most likely to get inappropriate low doses are those with renal dysfunction, those who are elderly or frail, are prone to falls and those with higher bleeding risk. Studies have shown that inappropriate low dosing does not reduce bleeding risk, and that efficacy for stroke prevention is attenuated, so it is extremely important to give the right dose to the patients based on the dosing criteria shown to improve outcomes in the clinical trials.

**Reference:** *JAMA Netw Open* 2023;6(6):e2317156

[Abstract](#)

## Cost-effectiveness of screening for paroxysmal atrial fibrillation in patients undergoing echocardiography

**Authors:** Ramkumar S et al.

**Summary:** This hypothetical study used a Markov model to investigate the cost-effectiveness of unselected age-based ECG screening for paroxysmal AF compared with selective screening based on an abnormal echocardiogram. The two strategies of portable ECG screening for AF were compared in the base case of a hypothetical asymptomatic 65-year-old male ( $CHA_2DS_2VASc = 3$  based on hypertension and diabetes mellitus) with previous echocardiography but without a cause for AF. With age-based screening, all patients underwent ECG. With imaging-guided screening, only those with left atrial (LA) volume  $\geq 34$  ml/m<sup>2</sup> and LA reservoir strain  $< 34\%$  or LV global longitudinal strain  $> -18\%$  underwent ECG screening. Costs, effects and incremental cost-effectiveness ratio were estimated for each screening strategy over a 20-year period. Imaging-guided screening was superior to age-based screening, with a lower cost (\$US54,823 vs \$US57,842) and better outcome (11.56 vs 11.52 quality-adjusted life-years over 20 years).

**Comment:** Opportunistic screening with ECG in older patients is recommended to detect asymptomatic AF, especially if they have risk factors for its development. This hypothetical study shows that screening targeted to patients with echocardiographic indicators of increased risk improves the detection rate of AF even further, and is cost effective. Unfortunately, there is no standardisation in echo reporting in Australia, but if echo reports could include this type of information and advice, AF detection would improve, and hopefully reduce the risk of AF-related strokes.

**Reference:** *Intern Med J* 2023;53(5):760-72

[Abstract](#)



\*First listed on the PBS, August 2012.<sup>3</sup>

<sup>†</sup>In patients with ACS, co-administered with aspirin, BRILINTA® reduced the risk of CV death, MI or stroke vs clopidogrel at 12 months (primary composite endpoint: ARR 1.9%, RRR 16%; p<0.001).<sup>1,2</sup>

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ACS, acute coronary syndrome; ADR, adverse drug reaction; AE, adverse effects; ARR, absolute risk reduction; CV, cardiovascular; MI, myocardial infarction; PBS, Pharmaceutical Benefits Scheme; PLATO, Platelet Inhibition and Patient Outcomes; RRR, relative risk reduction.

**References:** 1. Wallentin L, et al. *N Engl J Med.* 2009;361(11):1045–1057. 2. BRILINTA® Approved Product Information. 3. Pharmaceutical Benefits Scheme, Drug Utilisation Sub-Committee. Ticagrelor: analysis of predicted versus actual utilisation, Public Release Document. February 2016. Available at: <https://www.pbs.gov.au/industry/listing/participants/public-release-docs/2016-02/ticagrelor-dusc-prd-2016-02.pdf>. Accessed July 2022.

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## Long-term outcomes of women with peripartum cardiomyopathy having subsequent pregnancies

**Authors:** Pachariyanon P et al.

**Summary:** This retrospective study investigated adverse outcomes associated with subsequent pregnancies in women with peripartum cardiomyopathy (PPCM) during a previous pregnancy. Forty-five women (mean age 27 years) with subsequent pregnancies were included; 80% were of African American descent and 75.6% were from a low socioeconomic background. Clinical and echocardiographic findings were compared between women whose LVEF had recovered to  $\geq 50\%$  after the index pregnancy (recovery group;  $n=30$ ) and those whose LVEF remained  $<50\%$  after the index pregnancy (non-recovery group;  $n=15$ ). Overall, subsequent pregnancies were associated with a decrease in mean LVEF from 45.1% to 41.2% ( $p=0.009$ ). At 5 years, adverse outcomes were significantly higher in the non-recovery group than the recovery group (53.3% vs 20%;  $p=0.04$ ), driven by PPCM relapse. Five-year all-cause mortality was 13.33% in the non-recovery group and 3.33% in the recovery group ( $p=ns$ ).

**Comment:** PPCM is uncommon, but most patients with it have an improvement in LV function over time. The general advice is that if there has been an episode of PPCM, future pregnancies should be avoided due to the high likelihood of recurrence. This study supports these recommendations, and showed that even if the LV had recovered, subsequent pregnancy was associated with a high incidence of relapse, so that patients with recovered LV function after PPCM cannot be reassured it won't happen again. This study was done in a predominantly African American population, so its applicability to Australian women is not known, but it does support current recommendations.

**Reference:** *J Am Coll Cardiol* 2023;82(1):16-26

[Abstract](#)

## Association of beta-blocker therapy with cardiovascular outcomes in patients with stable ischemic heart disease

**Authors:** Godoy LC et al.

**Summary:** This Canadian study investigated the association between beta-blockers and cardiovascular events in patients with stable CAD. 28,039 patients aged  $>66$  years (mean 73 years, 66.2% male) with angiographically documented stable CAD without HF or a recent MI were included. 12,695 patients (45.3%) were newly prescribed beta-blockers. The 5-year risk of the primary composite outcome (all-cause mortality and hospitalisation for HF or MI) was 14.3% in patients taking beta-blockers and 16.1% in those not taking beta-blockers (HR 0.92, 95% CI 0.86–0.98;  $p=0.006$ ). The finding was driven largely by a reduction in MI hospitalisations.

**Comment:** It is guideline-directed medical therapy to prescribe beta-blockers post MI, with most guidelines recommending indefinite therapy in the absence of adverse effects. There has been a trend however, to stop these agents at 1–2 years post MI if the patient has undergone complete revascularisation, has no angina or arrhythmia and has normal LV function. This interesting study may make us want to reconsider this trend, as it showed that in stable patients with CAD, there was a reduction in cardiovascular events over 5 years, so maybe we should only discontinue beta-blockers for side effects rather than routine.

**Reference:** *J Am Coll Cardiol* 2023;81(24):2299-2311

[Abstract](#)

## Zilebesiran, an RNA interference therapeutic agent for hypertension

**Authors:** Desai AS et al.

**Summary:** Zilebesiran is a novel RNA interference agent that causes prolonged inhibition of hepatic angiotensinogen synthesis. This phase 1 study investigated the safety and efficacy of subcutaneous zilebesiran in patients with hypertension. 107 patients were randomised 2:1 to receive either a single ascending subcutaneous dose of zilebesiran (10, 25, 50, 100, 200, 400, or 800mg) or placebo and were followed for 24 weeks. Five patients had mild, transient injection-site reactions, but there were no reports of hypotension, hyperkalaemia, or worsening of renal function. Single doses of zilebesiran  $\geq 200$ mg were associated with  $>10$ mm Hg decreases in systolic BP and  $>5$ mm Hg decreases in diastolic BP by week 8; these changes were sustained at 24 weeks. The BP-lowering effects of zilebesiran 800mg were attenuated by a high-salt diet and augmented by coadministration with irbesartan.

**Comment:** Small interfering RNA (siRNA)-based therapies have been developed to reduce PCSK9 (inclisiran) and lipoprotein(a) (olpasiran) and are currently in phase 2–3 trials. To date they seem to be efficacious with no major adverse effects, but outcome trials are underway. This study reports an siRNA for hepatic angiotensinogen that is safe and effective in BP reduction, but larger safety and efficacy trials need to be done. Given these new agents, it seems we are entering a new age where inhibition of proteins at a cellular level is becoming feasible for many of the chronic conditions associated with cardiovascular disease, which has huge public health implications.

**Reference:** *N Engl J Med* 2023;389(3):228-38

[Abstract](#)

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## Accelerometer-derived “weekend warrior” physical activity and incident cardiovascular disease

**Authors:** Khurshid S et al.

**Summary:** This retrospective analysis of UK Biobank data investigated whether a “weekend warrior” pattern of exercising has similar cardiovascular benefits to a more evenly distributed pattern. Three patterns of moderate to vigorous physical activity (MVPA) were compared: active weekend warrior ( $\geq 150$  min, with  $\geq 50\%$  of total MVPA achieved in 1–2 days); active regular ( $\geq 150$  min, not meeting active weekend warrior status); and inactive ( $< 150$  min). A total of 89,573 individuals (mean age 62 years, 56% female) who provided a full week of accelerometer-based physical activity data in 2013–2015 were included. Multivariable-adjusted models showed that both active weekend warrior and active regular patterns of exercise were associated with similarly lower risks of incident AF, MI, HF, and stroke during follow-up.

**Comment:** It has traditionally been recommended that regular aerobic exercise should be done daily. This is often difficult for people of working age who are time poor during the working week. This interesting study suggests that it is the duration of exercise per week that matters, and that more prolonged exercise on a few days per week is as good as daily exercise with the same total duration of exercise time. This should be of enormous reassurance to those of us who can only find time to exercise on the weekends, but it is important to recognise that this entails just over an hour of exercise each day of the weekend to get the same benefit as 20 minutes per day.

**Reference:** *JAMA* 2023;330(3):247-52

[Abstract](#)

## Comparison of left bundle branch area pacing and biventricular pacing in candidates for resynchronization therapy

**Authors:** Vijayaraman P et al.

**Summary:** This observational study compared clinical outcomes after biventricular pacing (BVP) versus left bundle branch area pacing (LBBAP) in candidates for CRT. 1778 patients with LVEF  $\leq 35\%$  who were undergoing BVP or LBBAP for the first time for Class I or II indications for CRT at 15 international centres in 2018–2022 were included. After CRT, LVEF improved from 27% to 37% with BVP and from 27% to 41% with LBBAP ( $p < 0.001$ ). Multivariable regression analysis showed that the primary outcome (a composite of death or HF hospitalisation) was significantly reduced with LBBAP compared with BVP (20.8% vs 28%; HR 1.495, 95% CI 1.213–1.842;  $p < 0.001$ ).

**Comment:** Conventional CRT in patients with HFrEF involves placing a lead in the coronary sinus and advancing it to stimulate synchronised right ventricular and LV contraction, and has been shown to improve outcomes, symptoms, and LV function in patients with HFrEF (EF  $< 35\%$ ), particularly if they have left bundle branch block and QRS duration  $> 0.15$ ms. LBBAP is an attractive alternative to conventional CRT as it is more physiological, and this study shows that it is associated with better clinical outcomes. Although LBBAP can be technically more difficult to do than conventional CRT, it seems to be a better technique with respect to outcomes.

**Reference:** *J Am Coll Cardiol* 2023;82(3):228-41

[Abstract](#)

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