

# Cardiology Research Review™

Making Education Easy

Issue 162 - 2024

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### Abbreviations used in this issue:

ACS = acute coronary syndrome; AI = artificial intelligence;  
DAPT = dual antiplatelet therapy; ECG = electrocardiogram;  
ESUS = embolic stroke of undetermined source;  
HFrEF = heart failure with reduced ejection fraction; HR = hazard ratio;  
ICD = implantable cardioverter-defibrillator; LDL = low-density lipoprotein;  
MI = myocardial infarction; PCI = percutaneous coronary intervention;  
SGLT2 = sodium-glucose cotransporter 2; T2D = type 2 diabetes.

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

In this issue, findings from the FOURIER-OLE trial support the early initiation of intensive LDL cholesterol lowering in both patients with and without multivessel coronary artery disease, a post hoc analysis of the TALOS-AMI trial looks at DAPT de-escalation in stabilised MI patients after PCI, and the results of an English cohort study suggest that we should defer elective surgery for 12 rather than 6 months after a cardiovascular event. Also in this issue, two studies find that AI is likely to be increasingly helpful in managing patients with cardiovascular disease, and UK researchers investigate the potential mechanisms responsible for the beneficial effects of SGLT2 inhibitors in patients with HFrEF.

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

Kind Regards,

Associate Professor John Amerena

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## Long-term efficacy of evolocumab in patients with or without multivessel coronary disease

**Authors:** McClintick DJ et al.

**Summary:** The FOURIER trial reported that lipid-lowering therapy with evolocumab reduced the risk of major adverse cardiovascular events in patients with multivessel coronary artery disease. The FOURIER Open-Label Extension (FOURIER-OLE) investigated the use of evolocumab for an additional 5 years. 6635 patients who were randomised to evolocumab or placebo during the FOURIER trial entered the FOURIER-OLE and were followed up for an additional 5 years (median). Patients with coronary artery disease were categorised according to the presence or absence of multivessel disease ( $\geq 40\%$  stenosis in  $\geq 2$  large vessels). The primary end-point was cardiovascular death, MI, stroke, hospitalisation for unstable angina, or coronary revascularisation; the secondary end-point was cardiovascular death, MI, or stroke. Risk reduction with initial allocation to evolocumab tended to be greater in patients with multivessel disease than in those without: 23% vs 11% risk reduction for the primary end-point and 31% vs 15% risk reduction for the secondary end-point. The magnitude of risk reduction was greatest during the first few years, reaching 37–38% in patients with multivessel disease and 23–28% in patients without multivessel disease.

**Comment:** The FOURIER study showed that evolocumab reduced cardiovascular events in patients with established cardiovascular disease and an LDL of  $>2.6$  mmol/L on statin ± ezetimibe compared with placebo. This report on the outcome of high-risk patients with multivessel coronary artery disease included in the open-label extension study, showed that over another 5 years all patients benefited but those with multivessel disease had a greater risk of events than those without multivessel disease, and that the magnitude of benefit was greater and occurred earlier with evolocumab. Patients with multivessel disease and LDL  $>1.8$  mmol/L are now eligible for PBS subsidised treatment with evolocumab in Australia.

**Reference:** *J Am Coll Cardiol.* 2024;83(6):652–64

[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.

## Dual antiplatelet therapy de-escalation in stabilized myocardial infarction with high ischemic risk

**Authors:** Lee M et al., for the TALOS-AMI Investigators

**Summary:** This post hoc analysis of the TALOS-AMI trial compared a de-escalation strategy versus continued DAPT after PCI in post-MI patients. 2697 patients with stabilised MI who did not have any events during 1 month of ticagrelor-based DAPT after PCI were randomised to switch from ticagrelor to clopidogrel, or to remain on ticagrelor-based DAPT. De-escalation to clopidogrel was not associated with ischaemic outcomes (cardiovascular death, MI, ischaemic stroke, ischaemia-driven revascularisation, or stent thrombosis) compared with ticagrelor-based DAPT in patients at high ischaemic risk (HR 0.88, 95% CI 0.54–1.45;  $p=ns$ ) and in those not at high ischaemic risk (HR 0.65, 95% CI 0.33–1.28;  $p=ns$ ). De-escalation to clopidogrel was also not associated with increased bleeding risk.

**Comment:** The greatest risk of recurrent ischaemia after ACS is in the first 30 days after an event. Ticagrelor is the preferred P2Y<sub>12</sub> inhibitor post ACS with aspirin in Australia. This post hoc analysis of the TALOS study showed that changing ticagrelor to clopidogrel after 1 month was not associated with an increase in ischaemic events and had similar bleeding in patients with high-risk features for recurrent ischaemia compared to those who continued ticagrelor with or without high-risk characteristics. This is reassuring as sometimes it is necessary to change ticagrelor to clopidogrel due to side effects, cost or compliance issues.

**Reference:** *JAMA Cardiol.* 2024;9(2):125–33  
[Abstract](#)

## Risk of mortality following surgery in patients with a previous cardiovascular event

**Authors:** Chalitsios CV et al.

**Summary:** This retrospective cohort study investigated the time interval after a cardiovascular event that is associated with an increased risk of 30-day postoperative mortality. 877,430 patients with a prior ACS or stroke who underwent noncardiac, non-neurological surgery in England in 2007–2018 were included, and the primary outcome was 30-day all-cause mortality. Overall, patients were found to be at increased risk for postoperative mortality if their surgery was performed within 11.3 months of a previous cardiovascular event (within 14.2 months for elective surgery and within 7.3 months for emergency surgery). The absolute risk of 30-day postoperative mortality was greater after a stroke than after ACS.

**Comment:** It is common practice in Australia to delay elective surgery for 6 months or so after a cardiovascular event on the presumption that the patient has become “stable”. This study would suggest that this is not the case, and that there is increased postoperative mortality after an ACS, and even more so after stroke, in patients who undergo surgery within 12 months after an event. It is interesting that the mortality was higher after elective rather than emergency surgery, which could just reflect numbers, but could also be due to more intensive post-op monitoring in the emergency surgical group. This being the case, perhaps we should defer elective surgery for 12 rather than 6 months after a cardiovascular event.

**Reference:** *JAMA Surg.* 2024;159(2):140–9  
[Abstract](#)

## Physical activity and weight loss among adults with type 2 diabetes and overweight or obesity

**Authors:** Huang Z et al.

**Summary:** This post hoc analysis of the Look AHEAD trial examined the combined impact of weight loss and physical activity on the risk of adverse cardiovascular events in overweight or obese patients with T2D. Of 1229 participants (mean age 60 years, 43% male) in the Look AHEAD trial, 333 (27%) achieved and maintained weight loss for the first 4 years. Among those who maintained weight loss, 105 (32%) also maintained high physical activity volume. During a median 9.5 years of follow-up, patients who maintained both high physical activity volume and weight loss had a 61% lower risk of the composite cardiovascular end-point than those with low physical activity volume and no weight loss (HR 0.39, 95% CI 0.19–0.81;  $p=0.01$ ), but there was no significant risk reduction among those with only weight loss or only high physical activity.

**Comment:** The Look AHEAD study was a great disappointment as it was unable to show benefit of an intensive lifestyle intervention (physical activity and weight loss) in patients with T2D who were overweight or obese over an extended period of time. This interesting post hoc sub-analysis suggests that if the participants lost weight and did more exercise, they fared better than those who did not lose weight and did less exercise. It also showed that weight loss and exercise by themselves had no significant benefit, and it was only when both parameters changed that the outcome improved. We should thus emphasise to our patients the importance of both losing weight and exercising to improve outcomes.

**Reference:** *JAMA Netw Open* 2024;7(2):e240219  
[Abstract](#)

## Dynamic prediction of malignant ventricular arrhythmias using neural networks in patients with an implantable cardioverter-defibrillator

**Authors:** Kolk MZH et al.

**Summary:** This study reported the development of a dynamic machine learning model capable of using longitudinal ECG data to predict the risk of malignant ventricular arrhythmias in patients with ICDs. 2942 patients who received an ICD in 2007–2021 were included. In total, 32,129 ECG recordings were collected during a mean follow-up of 43.9 months. 840 (28.6%) patients had a malignant ventricular arrhythmia treated by the ICD during follow-up, and 631 (21.4%) died. Integrating longitudinal ECG-derived features within a dynamic machine learning model resulted in improved predictive accuracy: the mean time-varying area under the receiver operating characteristic curve was 0.738 for the dynamic model compared with 0.639 for a static model (i.e. baseline data only).

**Comment:** ICDs are implanted for both primary and secondary prevention but our ability to predict those patients who will go on to have an arrhythmia is not great. This AI model (machine learning and a neural network) was able to predict with more accuracy than traditional models which patients were more likely to have an arrhythmic event, by examining the resting ECGs of these patients. Should this be confirmed it will help risk stratify patients who are candidates for an ICD. In the future this type of analysis may get so accurate that implantation may be avoided in patients deemed to be low risk, but we are a long way from this at present.

**Reference:** *EBioMedicine* 2024;99:104937  
[Abstract](#)

CICM • ASM 2024  
WED 29th MAY 2024  
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Trainee Symposium  
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\*AREXVY is indicated for active immunisation of individuals 60 years and older for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV). Vaccines may not protect all recipients.<sup>1</sup>

## EFFICACY

HIGH EFFICACY AGAINST RSV-LRTD FOR YOUR PATIENTS AGED 60 YEARS AND OLDER.<sup>†1,2</sup>

OVERALL EFFICACY AGAINST RSV-LRTD.<sup>1,2</sup>  
PRIMARY ENDPOINT, VS. PLACEBO<sup>‡</sup>

82.6%

<sup>†</sup>(96.95% CI 57.9, 94.1).  
PRIMARY OBJECTIVE MET:  
LOWER CI LIMIT >20%.<sup>1,2</sup>

RSV-LRTD events: AREXVY 7/12,466; placebo 40/12,494.<sup>2</sup>

INDICATED EFFICACY AGAINST RSV-LRTD IN PATIENTS WITH ≥1 COEXISTING CONDITION OF INTEREST.<sup>1,2</sup>

SECONDARY DESCRIPTIVE ENDPOINT, VS. PLACEBO<sup>§</sup>

94.6%

<sup>†</sup>(95% CI, 65.9, 99.9);  
NO ADJUSTMENT FOR  
MULTIPLICITY,  
P VALUE NOT REPORTED.<sup>¶2</sup>

At baseline, 39% of participants had coexisting conditions of interest: COPD, asthma, any chronic respiratory or pulmonary disease, chronic heart failure, diabetes mellitus type 1 or type 2, advanced liver or renal disease.<sup>2</sup>

RSV-LRTD events: AREXVY 1/4,937; placebo 18/4,861.<sup>2</sup>

## SAFETY

AREXVY has an acceptable safety profile.<sup>2</sup>

Very common adverse events (≥10%) are headache, myalgia, arthralgia, injection site pain and fatigue. Common adverse events (≥1%) are injection site erythema, injection site swelling, fever, chills and rhinorrhoea (not a complete list; see full PI).<sup>1</sup>



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▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

PBS Information: AREXVY is not listed on the PBS or the National Immunisation Program (NIP).

<sup>†</sup>Ongoing, international, randomised, observer-blind, placebo-controlled, phase III trial to evaluate the efficacy of one dose of AREXVY (n=12,466) versus placebo (n=12,494) to prevent RSV-LRTD in adults ≥60 years of age during one RSV season (median follow-up 6.7 months, maximum follow up 10.1 months). RSV-LRTD was confirmed by RT-PCR and defined as presence for ≥24 hours of ≥2 lower respiratory symptoms or signs (including at least one sign) or ≥3 lower respiratory symptoms.<sup>2</sup>

<sup>‡</sup>The criterion for meeting the primary endpoint was a lower limit of the two-sided CI for vaccine efficacy >20%.<sup>2</sup>

<sup>§</sup>No adjustment for multiplicity was applied, so no inferences can be made without a hypothesis test.<sup>2</sup>

CI, confidence interval; COPD, chronic obstructive pulmonary disease; RSV, respiratory syncytial virus; RSV-LRTD, RSV-related lower respiratory tract disease; RT-PCR, reverse-transcriptase polymerase chain reaction.

**Dosing and administration:** AREXVY is administered as a single, reconstituted dose of 0.5 mL by intramuscular injection. The need for revaccination has not been established.<sup>2</sup>

**References:** 1. AREXVY Product Information. 2. Papi A et al. N Engl J Med 2023;388(7):595–608.

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PM-AU-RSA-JRNA-230005 | Date of approval: January 2024



## Artificial intelligence predicts undiagnosed atrial fibrillation in patients with embolic stroke of undetermined source using sinus rhythm electrocardiograms

**Authors:** Choi J et al.

**Summary:** This study reported the development and validation of an AI model for identifying undiagnosed paroxysmal AF in patients with ESUS. The AI model was developed using 737,815 sinus rhythm ECGs from patients with and without AF, and its diagnostic performance was tested in 352 patients with ESUS who were being monitored for AF using an insertable cardiac monitor. Over a 2-year follow-up period, 14.4% of the ESUS patients had an AF episode lasting  $\geq 1$ h. In the receiver operating curve analysis, the area under the curve for the AI model to identify AF  $\geq 1$ h was 0.806. The AI algorithm showed greater accuracy in identifying longer AF episodes, and the AI-AF risk score increased as the ECG recording approached the AF onset.

**Comment:** Anticoagulation with rivaroxaban and dabigatran has not been shown to reduce recurrent stroke risk in patients with ESUS but this study using AI analysing resting ECGs of patients who have had ESUS, suggests that patients at higher risk of developing AF can be detected by modelling, potentially identifying a subgroup of ESUS patients that may benefit from anticoagulation, even if AF is not clinically detected. This needs to be tested in randomised controlled trials but, as seen in the previous study, AI is likely to be increasingly helpful in managing patients with cardiovascular disease.

**Reference:** *Heart Rhythm* 2024; published online Mar 15

[Abstract](#)

## Apixaban for stroke prevention in subclinical atrial fibrillation

**Authors:** Healey JS et al., for the ARTESIA Investigators

**Summary:** The ARTESIA study investigated the efficacy of apixaban for stroke prevention in patients with subclinical AF. 4012 patients (mean 76.8 years, mean CHA<sub>2</sub>DS<sub>2</sub>-VASc score 3.9) with subclinical AF lasting 6 min to 24h were randomised in a double-blind, double-dummy design to receive apixaban 5mg twice daily (or 2.5mg twice daily if indicated) or aspirin 81mg once daily. The primary efficacy outcome was stroke or systemic embolism, and the primary safety outcome was major bleeding. During a mean follow-up of 3.5 years, stroke or systemic embolism occurred in 55 patients in the apixaban group and 86 patients in the aspirin group (HR 0.63, 95% CI 0.45–0.88;  $p=0.007$ ). Major bleeding was more common with apixaban (HR 1.80, 95% CI 1.26–2.57;  $p=0.001$ ).

**Comment:** This study answers the very important question as to the burden of AF that justifies anticoagulation in patients who are at risk of stroke (mean CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 3.9 in this study). Before this study,  $<6$  min of AF was thought not to be sufficient to recommend long-term anticoagulation, but if  $>24$ h then anticoagulation was recommended, leaving uncertainty about what to do if AF duration was between 6 min and 24h. This study clearly shows that AF duration between 6 min and 24h is associated with an increased risk of stroke, although not as great as AF burden  $>24$ h. It also showed that anticoagulation significantly reduced this stroke risk, albeit at the price of more bleeding. This has profound implications as subclinical AF is often detected on interrogation of permanent pacemakers, ICDs or cardiac resynchronisation therapy, and if it is of 6-min duration or greater these results suggest anticoagulation is beneficial. It would be nice to see the relationship between baseline CHA<sub>2</sub>DS<sub>2</sub>-VASc score and benefit, as it may be that only the highest CHA<sub>2</sub>DS<sub>2</sub>-VASc patients derive benefit.

**Reference:** *N Engl J Med* 2024;390:107–17

[Abstract](#)

## Pulmonary vein isolation with or without left atrial appendage ligation in atrial fibrillation

**Authors:** Lakkireddy DR et al., for the aMAZE Investigators

**Summary:** The aMAZE trial investigated the efficacy and safety of percutaneous left atrial appendage ligation adjunctive to catheter pulmonary vein isolation in patients with nonparoxysmal AF. Eligible patients were randomised 2:1 to undergo left atrial appendage ligation and pulmonary vein isolation ( $n=404$ ) or pulmonary vein isolation alone ( $n=206$ ). The primary outcome (freedom from documented atrial arrhythmias of  $>30$ -sec duration at 12 months) was achieved by 64.3% of patients receiving left atrial appendage ligation plus pulmonary vein isolation compared with 59.9% receiving pulmonary vein isolation only ( $p=ns$ ). The 30-day serious adverse event rate was 3.4%. Twelve months after pulmonary vein isolation, complete left atrial appendage closure was maintained in 84% of patients, with 99% having  $\leq 5$ mm residual communication.

**Comment:** This study examined whether left atrial appendage isolation by ligation offered any benefit in reducing AF burden when done at the same time as an AF ablation with pulmonary vein isolation. Although it was safe to do so there was no benefit in reducing recurrent AF, so this procedure should not be performed to reduce AF burden but could be considered to reduce stroke risk in patients who cannot take anticoagulants whose CHADSVA risk is  $\geq 2$ .

**Reference:** *JAMA* 2024;331(13):1099–1108

[Abstract](#)



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## Sex-specific association between perivascular inflammation and plaque vulnerability

**Authors:** Kinoshita D et al.

**Summary:** This study investigated whether the association between perivascular inflammation and plaque vulnerability differs between sexes. 409 patients (80% male) who underwent computed tomography coronary angiography (CTCA) and optical coherence tomography (OCT) were included. The level of perivascular inflammation was assessed by pericoronary adipose tissue attenuation on CTCA and the level of plaque vulnerability was assessed by OCT, and patients were grouped into tertiles according to culprit vessel pericoronary adipose tissue attenuation (low inflammation [ $\leq -73.1$  HU]; moderate inflammation [ $-73.0$  to  $-67.0$  HU]; and high inflammation [ $\geq -66.9$  HU]). Analysis of the data revealed that perivascular inflammation was significantly associated with plaque vulnerability in women, with a higher prevalence of thin-cap fibroatheroma and greater macrophage grades in the high inflammation group compared with the low inflammation group. No significant differences were observed between the three tertiles in men.

**Comment:** We know there are differences in atherosclerotic vascular disease between men and women. This interesting study showed that in women who underwent CTCA and OCT of their coronary vessels, there was overall less plaque burden in women than men, but if there was perivascular inflammation, there was more likely to be thin cap fibroatheroma (as a surrogate for less plaque stability) in women, whereas there was no relationship between inflammation and thin-cap fibroatheroma in men. The women in this study were older, which may have influenced this finding, and it would be interesting to see if there were differences in markers of inflammation such as high-sensitivity C-reactive protein or interleukin-6 between the groups studied.

**Reference:** *Circ Cardiovasc Imaging* 2024;17(2):e016178  
[Abstract](#)

## Sodium-glucose cotransporter 2 inhibitors influence skeletal muscle pathology in patients with heart failure and reduced ejection fraction

**Authors:** Wood N et al.

**Summary:** This study investigated the effects of SGLT2 inhibitors on skeletal muscle pathology in patients with HFrEF. Skeletal muscle biopsies from 28 male patients with HFrEF (NYHA class I–III) were compared; 12 men had been treated with SGLT2 inhibitors for >12 months and 16 were untreated controls. Various state-of-the-art techniques (from structural imaging to metabolomics) revealed that treatment with SGLT2 inhibitors was associated with anti-atrophic, anti-inflammatory, and pro-metabolic effects, with myofibre atrophy being approximately 20% lower in the men taking SGLT2 inhibitors. These changes may be regulated via interleukin-6–kynurenine signalling.

**Comment:** The mechanism of the beneficial effects of SGLT2 inhibitors apart from glucose lowering has remained elusive. It has been postulated that there are effects on free fatty acid production and utilisation, and that there are effects on Na/H exchanger at a cellular level that affects intracellular metabolism, but this has not been proven. This interesting study shows that there are effects on skeletal muscle morphology via interleukin-6–kynurenine signalling that seem to be favourable and may explain some of the benefit. It would be of interest to see if the same changes are seen in myocardial muscle, given the improvement in ejection fraction and remodelling that has been documented with the SGLT2s.

**Reference:** *Eur J Heart Fail.* 2024; published online Mar 11  
[Abstract](#)

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