Cardiology Practice Review™

Making Education Easy

Issue 13 - 2021

In this issue:

Abbreviations used in this review:

ATAGI = Australian Technical Advisory Group on Immunisation; **CAC** = coronary artery calcium; **MBS** = Medicare Benefits Schedule; **PBAC** = Pharmaceutical Benefits Advisory Committee; **PBS** = Pharmaceutical Benefits Scheme; **TGA** = Therapeutic Goods Administration.

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Welcome to the 13th issue of Cardiology Practice Review.

This Review covers news and issues relevant to clinical practice in cardiology. It will bring you the latest updates, both locally and from around the globe, in relation to topics such as new and updated treatment guidelines, changes to medicines reimbursement and licensing, educational, medicolegal issues, professional body news and more. And finally, on the back cover you will find our COVID-19 resources for Cardiologists and a summary of upcoming local and international educational opportunities including workshops, webinars and conferences.

We hope you enjoy this Research Review publication and look forward to hearing your comments and feedback.

Kind Regards,

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Clinical Practice

National Heart Foundation of Australia position statement on coronary artery calcium scoring for the primary prevention of cardiovascular disease

This position statement considers new evidence on the use of coronary artery calcium scoring (CAC) for measuring cardiovascular risk and offers advice to health professionals on the use of CAC scoring in primary prevention of cardiovascular disease in Australia.

The Heart Foundation's position is that CAC scoring can have a role in reclassification of absolute cardiovascular risk for patients in Australia, along with traditional absolute risk assessment and as part of a shared decision-making approach that considers the choices of each patient.

Suggested approach to CAC measurement in practice

Before considering CAC scoring, assess clinical CVD risk. If the person is aged over 45 years (or over 30 years if Aboriginal or Torres Strait Islander), incorporate a National Vascular Disease Prevention Alliance (NVDPA) absolute risk assessment. Note that the 2012 NVDPA absolute risk algorithm may underestimate risk in some patients, such as Aboriginal and Torres Strait Islander peoples, or in others with risk features not included in the NVDPA algorithm. Such risk features include: family history of premature atherosclerotic CVD; primary hypercholesterolaemia (LDL ≥4.1 mmol/L, non-HDL ≥4.9 mmol/L); persistently elevated triglyceride levels (>1.98 mmol/L); metabolic syndrome; history of premature menopause or pregnancy-associated conditions that increase atherosclerotic CVD risk (e.g., preeclampsia); chronic inflammatory conditions; high risk ethnicity (e.g., south Asian populations, Aboriginal and Torres Strait Islander peoples); other lipids or biomarkers associated with increased atherosclerotic CVD risk. CAC scoring could be considered in some instances to reclassify risk.

CAC scoring is not required in people already determined to be at high absolute cardiovascular risk. It may be considered in people with moderate risk for whom management intensity is uncertain, e.g., when the initial risk status is near the threshold for high-risk status.

A CAC score of 0 Agatston units (AU) could reclassify a moderate risk person to low absolute risk, but does not exclude the presence of non-calcified plaque. Be aware of underestimating risk in the presence of certain risk-enhancing factors (e.g., Aboriginal and Torres Strait Islander population, cigarette smoking, diabetes, and a family history of CVD). Subsequent risk management strategies should be decided after patient–clinician discussion and follow modern guidelines for absolute CVD risk (e.g., the 2012 NVDPA guidelines). An interval of 5 years is reasonable for repeat CAC score.

In the case of CAC score 1–99 AU and <75th percentile for age and sex, reclassification of risk status is uncertain.

CAC scores >99 AU or ≥75th percentile for age and sex could reclassify a person to high absolute risk status. Repeat CAC testing is not recommended in this group. Further risk management strategies, including the use of antihypertensive and lipid-lowering therapies, should follow guidelines for management of absolute CVD risk (2012 NVDPA absolute CVD risk guidelines and the 2016 Heart Foundation hypertension guidelines).

https://tinyurl.com/4sbc49bw

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ATAGI guidance on myocarditis and pericarditis after mRNA COVID-19 vaccines

The Australian Technical Advisory Group on Immunisation (ATAGI) has updated their guidance on myocarditis and pericarditis following mRNA COVID-19 vaccination, in a joint statement with the Cardiac Society of Australia and New Zealand (CSANZ), the Royal Australian College of General Practitioners (RACGP), the Australian College of Remote and Rural Medicine (ACRRM), and the Australasian College of Emergency (ACEM).

What has been updated

- Information on the rate of myocarditis or pericarditis associated with mRNA vaccines.
- Precautions for people with a past history of pericarditis or myocarditis; 'recent' myocarditis or pericarditis is now defined as within the last 3 months (previously 6 months).
- Guidance on assessment and referral of suspected myocarditis or pericarditis in primary care and emergency departments.
- Guidance on revaccination after myocarditis or pericarditis.

Key points

An increased risk of pericarditis and/or myocarditis has been observed in people who have received an mRNA COVID-19 vaccine (Comirnaty [Pfizer] and Spikevax [Moderna]), compared to unvaccinated people. COVID-19 itself is associated with a higher risk of myocarditis compared with mRNA vaccination. COVID-19 is estimated to be associated with myocarditis at a rate of 11.0 events per 100,000 persons, whilst Comirnaty (Pfizer) vaccine has been estimated to cause myocarditis at a rate of 2.7 events per 100,000 persons. Therefore, the benefits of vaccination in protecting against COVID-19 outweigh the risk of myocarditis and/or pericarditis. mRNA vaccines continue to be recommended for all people aged 12 years and older. Vaxzevria (AstraZeneca) is not associated with an increased risk of myocarditis and/or pericarditis.

Pericarditis and myocarditis after mRNA COVID-19 vaccines occur most commonly in males under 30 years of age, and most commonly after the second vaccine dose. Most cases have been mild and patients have recovered quickly. Longer-term follow-up is ongoing.

Pre-existing cardiac conditions are not regarded as a contraindication to vaccination. People with a history of any of the following conditions can receive an mRNA vaccine but should consult a GP, immunisation specialist or cardiologist regarding the best timing of vaccination and whether any additional precautions are recommended:

- Recent (i.e., within the last 3 months) myocarditis or pericarditis due to causes other than vaccination.
- Acute rheumatic fever or acute rheumatic heart disease (i.e., with evidence of active inflammation).
- Acute decompensated heart failure.

Symptoms of myocarditis or pericarditis usually start within 1-5 days of mRNA vaccination and include chest pain, palpitations, syncope, or shortness of breath. People with any of these symptoms should seek urgent medical attention.

Initial assessment can be conducted in a general practice or an outpatient cardiology setting for patients who are not acutely unwell and when results can be obtained and reviewed within 12 hours. Initial investigations should include ECG and blood troponin levels. A chest X-ray, and other investigations may be indicated. Some patients may require review in an emergency department.

Further doses of an mRNA COVID-19 vaccine can be given to people who have been investigated for pericarditis but who had normal ECG, troponin and inflammatory markers, and who have been symptom-free for at least 6 weeks. This includes people with a clinical diagnosis of pericarditis despite normal investigations.

For people with suspected or proven pericarditis and abnormal investigation results, the need and choice of further doses is informed by age and sex:

- Male 12-14 years - do not proceed with second vaccination.
- Females 12-59 years and males 25-59 years:
  - <30 years - consider alternative vaccine (Vaxzevria not licensed for <18 years old).
  - >30 years - consider second dose of mRNA vaccination vs Vaxzevria.
- ≥60 years (any sex) - proceed with a second dose of Vaxzevria.

People who have had confirmed myocarditis after mRNA vaccination should defer further doses of an mRNA COVID-19 vaccine and if they are ≥18 years can consider Vaxzevria on a case-by-case basis, after they have recovered from their symptoms.

https://tinyurl.com/hcy7dfda

Regulatory News

PBS listings

Alirocumab (Praluent®) has been listed on the PBS for the treatment of non-familial hypercholesterolaemia in patients with atherosclerotic cardiovascular disease and additional high-risk factors.

PBAC recommendations

The PBAC has recommended extending the existing PBS listing of **dapagliflozin** (Forxiga®) to include a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with heart failure with reduced ejection fraction. However it is not yet reimbursed by the PBS for this indication.

TGA – new registrations

Inclisiran (Leqvio®) is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with heterozygous familial hypercholesterolaemia, atherosclerotic cardiovascular disease, or at high risk of a cardiovascular event:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or,
- alone or in combination with other lipid-lowering therapies in patients who are statin intolerant.

TGA alerts

Shortage of Imdur Durules and Monodur Durules isosorbide mononitrate 120 mg modified release tablets

The TGA has been notified of shortages of Imdur Durules and Monodur Durules isosorbide mononitrate 120 mg modified release tablets. The shortages are expected to continue until 19 December 2022. The tablets are indicated for the prophylactic treatment of angina pectoris.

The TGA has made a Serious Scarcity Substitution Instrument (SSSI) to help patients access their medicine from their pharmacist without delay, ensure treatment is not interrupted and relieve workload pressure on prescribers and pharmacists.

The SSSI has been made from 18 September 2021 until 19 December 2022 to:

- Declare 120 mg isosorbide mononitrate modified release tablets as scarce medicines; and
- Specify medicines that contain 60 mg isosorbide mononitrate modified release tablets as substitutable medicines that pharmacists are permitted to dispense in substitution.

When issuing new prescriptions, prescribers should be aware of the shortage of isosorbide mononitrate 120 mg modified release tablets. The PBS listing for isosorbide mononitrate 60 mg modified release tablets provides a maximum of 30 tablets, as a monthly supply. Contact Services Australia to request increased maximum quantity, so the PBS script is valid.

https://tinyurl.com/3rrdjh8x

Azide impurity in 'sartan' blood pressure medicines

The TGA is investigating contamination of some 'sartan' medicines with unacceptable levels of an azide impurity, azidomethyl-biphenyl-tetrazole (AZBT). Very low levels of this impurity have been found in batches of losartan and irbesartan products, and these have been recalled from pharmacies.

AZBT can form during the manufacture of the active ingredient in some sartan medicines. It is known to damage DNA, and long-term exposure over years may increase an individual's risk of developing cancer.

The risk posed by AZBT at the levels detected in sartan medicines is very low. However, such contamination is unacceptable for a medicine. Health professionals should be aware of this impurity issue and advise patients accordingly. There is no reason to stop prescribing sartans. However, there may be limited availability of some sartans due to current shortages.

Patients should be reminded of the importance of controlling their blood pressure and reassured that the risk posed by the impurity at the trace levels observed to date is very low.

https://tinyurl.com/bc9pytbr

MBS updates

On 1 November 2021, a new MBS item was made available for diagnosis of hypertension through ambulatory blood pressure monitoring for individuals with suspected hypertension. The purpose of the service is to monitor blood pressure continuously over 24 hours via a wearable device. The service includes the fitting of the device, analysis of the data, generation of a report and development of a treatment plan and all consultations associated with the service.

Four new MBS items became available in July for the provision of transcatheter mitral valve repair using the MitraClip™ implant for managing severe mitral valve regurgitation. Eligible patients are those who cannot undergo open surgical management with moderate-severe mitral valve regurgitation and require a less invasive approach.

In July, changes were made to modernise cardiac surgical services to ensure they reflect current medical practice, support high-value care and ensure patients receive current best practice. The changes include updates to item descriptors, combining similar surgical procedures, introducing items that represent a complete medical service, incentivising advanced techniques, removal of procedures that no longer reflect best practice, and reducing low value invasive angiography and ineffective coronary artery stenting.

A minor change to two interim MBS items for heart health assessment were made in July. The amended items include item 699 for a heart health assessment by a GP at consulting rooms lasting at least 20 minutes, and item 177 for heart health assessment by a medical practitioner (other than a specialist or consultant physician) at consulting rooms lasting at least 20 minutes. The interim items have been extended until 30 June 2023 and amended to limit the services to patients who are older than 30 years.

COVID-19 Resources for Cardiologists

CSANZ https://tinyurl.com/y3xp2729
ACC https://tinyurl.com/y68aud3a
ESC https://tinyurl.com/wn3fsts

Conferences, Workshops and CPD

Please click on the links below for upcoming local and international Cardiology meetings, workshops and CPD.

ACRA Events https://tinyurl.com/y4yj8xb5
CSANZ CPD https://tinyurl.com/yaq367md
Cardiac Skills Australia https://tinyurl.com/zkzlelb
Heart Foundation https://tinyurl.com/y34smdoz
Australian Centre for Heart Health https://tinyurl.com/y3xac46d
ACC https://tinyurl.com/y2khytpz
AHA https://tinyurl.com/zajc9a7
ESC Congresses and Events https://tinyurl.com/y6ko68yf
ESC Education https://tinyurl.com/y3zkjp3o

News in Brief

Patients with acute myocarditis following mRNA COVID-19 vaccination

This paper addresses the association of mRNA-based COVID-19 vaccination and myocarditis. The study is an audit of myocarditis and previous mRNA vaccination at a single US centre. As there was no control group, the rate of myocarditis could not be calculated. However, they identified 4 patients who developed myocarditis within 5 days of their second COVID-19 vaccination (2 after the Moderna vaccine and 2 after the Pfizer-BioNTech vaccine). Three were younger males (age 23–36 years) and 1 was an older female (age 70 years). All had severe chest pain, abnormal electrocardiogram and troponin elevation. Cardiac MRI findings were typical for myocarditis, and other tests provided no alternative explanation.

https://tinyurl.com/wv7m682p

Statin use and mortality in atrial fibrillation

This systematic review and meta-analysis evaluated the effects of statin therapy on mortality in patients with non-valvular AF. A search identified 14 studies (2 post-hoc analyses of randomised clinical trials, 8 prospective and 4 retrospective) that reported the efficacy of statins in 100,287 AF patients (23,228 were taking a statin). An effect was measurable within 12 months, and the absolute risk for all-cause mortality was reduced by 10%. In terms of relative risk, all-cause mortality was reduced by 41% and cardiovascular mortality by 25%. The authors ask for implementing this finding into the guidelines and recommend statins for AF patients.

https://tinyurl.com/3mh4wxfu

Associations between statins and adverse events in primary prevention of cardiovascular disease

This systematic review and meta-analysis examined the tolerability profile of statins when used for primary prevention. A search identified 62 randomised controlled trials of statins involving 120,456 patients without a history of CV disease. During a mean follow-up of 3.9 years, statins were associated with an increased risk of self-reported muscle symptoms (OR 1.06, 95% CI 1.01–1.13), liver dysfunction (OR 1.33, 95% CI 1.12–1.58), renal insufficiency (OR 1.14, 95% CI 1.01–1.28), and eye conditions (OR 1.23, 95% CI 1.04–1.47), but were not associated with clinically confirmed muscle disorders or diabetes. The increased risks did not outweigh the reduction in risk of major CV events. Few significant differences were found between the different statins.

https://tinyurl.com/7txy5jyx

Guided versus standard antiplatelet therapy in patients undergoing percutaneous coronary intervention

This systematic review and meta-analysis investigated the safety and efficacy of guided versus standard selection of antiplatelet therapy in patients undergoing PCI. A search identified 11 randomised controlled trials and 3 observational studies (n=20,743). Co-primary endpoints were trial-defined primary MACE and any bleeding. Compared with standard therapy, guided selection of antiplatelet therapy was associated with a significant reduction in MACE (RR 0.78, 95% CI 0.63–0.95; p=0.015) and a nonsignificant reduction in bleeding (RR 0.88, 95% CI 0.77–1.01; p=0.069). Cardiovascular death, MI, stent thrombosis, stroke and minor bleeding were all reduced with guided therapy compared with standard therapy, but risks of all-cause death and major bleeding did not differ between groups.

https://tinyurl.com/9xbsppdn

Research Review Publications

Acute Coronary Syndrome Research Review
with Professor John French
http://tinyurl.com/gos7bqt

Atrial Fibrillation Research Review
with Dr Andre Catanchin
http://tinyurl.com/gpvl4dv

Cardiology Research Review
with Associate Professor John Amerena
http://tinyurl.com/gpxu6bl

Heart Failure Research Review
with Professor Peter Macdonald and Dr John Atherton
http://tinyurl.com/hxxrsv6

Interventional Cardiology Research Review
with Conjoint Professor Craig Juergens
http://tinyurl.com/h3h3wcp

CSANZ 2021 Conference Review
https://tinyurl.com/v2daava9

ESC Congress 2021 The Digital Experience
https://tinyurl.com/36psr7t3

Educational Series – Challenge of cardiac adverse reactions with cancer immunotherapy
https://tinyurl.com/562xv2kp

Educational Series – RNA therapies in cardiovascular medicine
https://tinyurl.com/eshhju4z

Product Review – Macitentan in patients with pulmonary arterial hypertension
https://tinyurl.com/35yena4w

Product Review – Rosuvastatin calcium in patients with hypercholesterolaemia
https://tinyurl.com/2cftt75c

Speaker Series – Patient selection and practicalities of using selexipag in PAH
https://tinyurl.com/22frmry4

Study Review – Bleeding risk with oral anticoagulants in geriatric patients
https://tinyurl.com/dfs5bnwy

Study Review – JUPITER, preventing vascular events in people with elevated C-reactive protein
https://tinyurl.com/2rfsa78x

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