

Cardiology Practice Review™

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Issue 15 - 2022

In this issue:

- > Management of AF in patients ≥ 75 years
- > ESC guidelines: Cardiac pacing and resynchronisation
- > ESC/EACTS guidelines: Valvular heart disease
- > USPSTF: Screening for AF
- > PBS listings
- > PBAC recommendations
- > TGA – new and extended registrations
- > MBS news
- > COVID-19 vaccination–associated myocarditis in adolescents
- > Myocarditis after mRNA COVID-19 vaccine
- > AHA: Comprehensive management of CV risk factors in T2D
- > COVID-19 resources
- > Conferences, workshops and CPD

Abbreviations used in this review:

AF = atrial fibrillation; **AHA** = American Heart Association;
EACTS = European Association for Cardio-Thoracic Surgery;
ESC = European Society of Cardiology;
MBS = Medicare Benefits Schedule;
PBAC = Pharmaceutical Benefits Advisory Committee;
PBS = Pharmaceutical Benefits Scheme;
TGA = Therapeutic Goods Administration;
USPSTF = US Preventive Services Task Force.

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Welcome to the 15th 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

Management of atrial fibrillation in patients 75 years and older

In this paper, major trials and society guidelines regarding the care of atrial fibrillation in patients 75 years and older were reviewed to understand outcomes and evidence-based approaches to management in this population.

Older patients with atrial fibrillation typically have high risk of stroke, bleeding and death, but the risk of falls is rarely a contraindication to anticoagulation in these patients.

A shared decision–making approach is critical to management of atrial fibrillation in older adults, with a focus on primary and secondary prevention of risk factors, avoiding adverse drug reactions, reduction of stroke risk, reduction of bleeding risk, and avoiding under-prescription of oral anticoagulants.

Regarding adverse drug reactions, digoxin may be useful for rate control, but associations with increased mortality limit its use. Serum digoxin concentration should be <1.2 ng/mL. Syncope and falls injuries are higher with the use of antiarrhythmic drugs, especially amiodarone.

Beyond rate and rhythm control considerations, stroke prophylaxis is key to atrial fibrillation management, and the benefits of direct oral anticoagulants, compared with warfarin, extend to older adults.

Invasive procedures such as atrial fibrillation catheter ablation, pacemaker implantation/atrioventricular junction ablation, and left atrial appendage occlusion may be useful for some patients. However, older adults have usually been under-represented in clinical trials.

<https://tinyurl.com/you9mx2pf>

ESC guidelines on cardiac pacing and cardiac resynchronisation therapy

The European Society of Cardiology (ESC) guidelines on cardiac pacing and cardiac resynchronisation therapy (CRT) have recently been published.

The paper outlines changes in indications and pacing methods that have occurred since 2013 when the previous ESC pacing guidelines were published. They include new approaches to pacing in various settings of syncope that are related to abnormal reflexes originating from the brain (neurally mediated syncope). Several indications for CRT in heart failure have been updated. In addition, there are new sections on pacing after transcatheter aortic valve implantation (TAVI) and following heart surgery. A new section encompasses sex differences, reflecting the fact that pacing indications and complication rates differ between male and female patients.

Regarding decision-making on whether or not a device is needed, the guidelines now include an entire chapter to this area including novel diagnostic tools and which tests to perform in certain settings. For example, cases where it is necessary to look for underlying heart disease with certain blood tests, when to conduct genetic tests and cardiac imaging, and when to perform prolonged monitoring using wearable or implantable devices to detect intermittent rhythm disorders requiring pacing.

Specific recommendations are offered on how to reduce complications. For example, preoperative administration of antibiotics within one hour of skin incision is recommended to reduce the risk of device-related infection, while chlorhexidine alcohol should be considered for skin antisepsis at the incision site. Rinsing the pocket device with saline should be considered. In certain settings, use of an antibiotic-eluting envelope may be considered for patients undergoing a re-operation on their device. Permanent pacemaker implantation is not recommended in patients with fever, but should be delayed until the patient is afebrile for at least 24 hours.

Recommendations are provided on how to manage patients with pacemakers in certain situations, such as when MRI or irradiation are required. A flowchart is provided to aid decision-making according to the particular pacing system. Similarly, most pacemaker patients requiring irradiation can undergo therapy with appropriate precautions and evaluation afterwards.

Regarding follow-up, remote monitoring of devices improves the identification of technical issues including battery depletion and clinical problems such as arrhythmias. The guidelines recommend remote device management for patients with difficulties attending in-clinic appointments and when a device component is at higher risk of a technical problem to allow early detection.

<https://tinyurl.com/2p86wm9w>

ESC/EACTS guidelines for the management of valvular heart disease

The European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) guidelines for the management of valvular heart disease (VHD) have recently been published.

Treatments for VHD include medication and percutaneous or surgical valve replacement/repair. The choice and timing of treatment depends on clinical and anatomical characteristics, comorbidities, and patient preferences, and should be agreed upon by a Heart Team of clinical and interventional cardiologists, cardiac surgeons, imaging specialists, cardiovascular anaesthesiologists, and nurses.

Symptomatic patients should undergo interventions (percutaneous or surgery) if there is an expected benefit. Treatment decisions in asymptomatic patients must consider the risk of intervention against the expected natural history of VHD – if rapid symptom progression is expected, intervention may be acceptable if the procedural risk is low. In elderly patients, treatment decisions should consider the impact of treatment on life expectancy and quality of life.

The updated guidelines include expanded indications for earlier surgery in asymptomatic patients with aortic stenosis, aortic regurgitation or mitral regurgitation. The requirement for more thorough evaluation and earlier surgery in patients with tricuspid regurgitation is highlighted, to avoid irreversible heart damage.

Regarding percutaneous techniques, evidence for benefit in high risk or inoperable patients with aortic stenosis and mitral regurgitation has led to expanded indications, in the absence of futility. Early data with transcatheter tricuspid valve interventions suggests a beneficial role for patients who cannot undergo surgery, but this needs to be confirmed by further studies.

The guidelines note that high volumes of procedures are required to deliver good quality care, but exact numbers per clinician or hospital remain controversial due to inequalities between high- and middle-income countries.

<https://tinyurl.com/2p8zhsev>

Screening for atrial fibrillation - US Preventive Services Task Force recommendation statement

The US Preventive Services Task Force (USPSTF) has reviewed evidence for atrial fibrillation (AF) screening, and reached a similar conclusion in the 2022 update to its 2018 screening recommendation: There is insufficient evidence on both the harms and benefits of one-time preventive screening for AF to recommend for or against screening for adults 50 years and older without a diagnosis or symptoms of AF, as well as no history of transient ischaemic attack or stroke.

According to the USPSTF statement, "AFib is a major risk factor for ischemic stroke and is associated with a substantial increase in the risk of stroke. Approximately 20% of patients who have a stroke associated with AFib are first diagnosed with AFib at the time of the stroke or shortly thereafter."

The review undertaken by the USPSTF evaluated evidence published through October 31, 2021 that included 113,784 patients. Important questions on the risks and benefits of screening for AF, detecting AF, screening accuracy, and the benefits and harms of anticoagulation were examined:

- Does screening for AF with selected tests improve health outcomes (i.e., reduce all-cause mortality, reduce morbidity or mortality from stroke, or improve quality of life) in asymptomatic older adults?
- Does systematic screening for AF with selected tests identify older adults with previously undiagnosed AF more effectively than usual care?
- What is the accuracy of selected screening tests for diagnosing AF in asymptomatic adults?
- What are the harms of screening for AF with selected tests in older adults?
- What are the benefits of anticoagulation therapy on health outcomes in asymptomatic, screen-detected older adults with AF?
- What are the harms of anticoagulation therapy in asymptomatic, screen-detected older adults with AF?

Despite the review finding that unknown cases of AF can be detected more often via screening, evidence remains limited on how health outcomes can be affected. Furthermore, there remains a risk of major bleeding from anticoagulation, and since the USPSTF's 2018 screening recommendation, no new trials have examined the effect of anticoagulation on screening-detected AF.

The USPSTF states that AF is the most frequent cardiac arrhythmia, a major risk factor for ischaemic stroke, and linked with increased stroke risk because it often remains undetected. Stroke may also be the first sign of AF. Therefore, treatment usually includes symptom management and stroke prevention. Anticoagulation reduces the risk of stroke, and the USPSTF's review for the 2022 update investigated automated blood pressure cuffs, pulse oximeters, smartwatches and smartphone apps as further screening methods.

An accompanying editorial noted that the European Society of Cardiology (ESC) came to a different conclusion in its 2020 guideline on diagnosis and management of AF: The ESC recommends AF screening due to the potential for benefit from early detection and treatment in some older individuals. The editorial notes that since 2018, only two trials have investigated AF screening compared to nonscreening with regards to clinical outcomes and states that more data are needed for the USPSTF to recommend for or against screening for AF.

Another editorial points out that although AF screening has important implications for public health, an overall recommendation for individuals above a certain age may not be required. Instead, specific individualised recommendations may be a better approach, including "assessing the burden of AF, rather than the presence or absence of it", and detecting and monitoring individuals at higher risk for AF.

<https://tinyurl.com/yp5p86ek>

<https://tinyurl.com/2p8943mk>

<https://tinyurl.com/3ju5c8a3>

<https://tinyurl.com/2p99n6cv>

<https://tinyurl.com/2p8d9e4f>

Regulatory News

PBS listings

The existing PBS listing of **dapagliflozin** (Forxiga®) has been expanded to include a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with heart failure with reduced ejection fraction.

<https://tinyurl.com/bddpffwk>

PBAC recommendations

The PBAC made the following recommendations at its November meeting. Of note, neither of these drugs are reimbursed on the PBS for the below indications:

- The PBS listing of **empagliflozin** (Jardiance®) for the treatment of patients with chronic heart failure with reduced ejection fraction, New York Heart Association classification II-IV, left ventricular ejection fraction $\leq 40\%$, who are receiving standard care including a beta blocker, and an angiotensin-converting enzyme inhibitor, or an angiotensin II receptor blocker, or an angiotensin receptor with neprilysin inhibitor.
- An amendment to the authority requirements for continuing treatment for **riociguat** for chronic thromboembolic pulmonary hypertension from Authority Required (Written) to Authority Required (Telephone/Electronic) noting the stable market, the robustness of the initial written restriction criteria and for consistency with the level of authority of the PBS restrictions for medicines to treat pulmonary arterial hypertension.

<https://tinyurl.com/4kwfypm3>

TGA – new and extended registrations

Empagliflozin (Jardiance®) is now also indicated in adults for the treatment of symptomatic heart failure with reduced ejection fraction, as an adjunct to standard of care therapy.

<https://tinyurl.com/2p8d9eub>

Vericiguat (Verquvo®) is indicated in addition to standard of care therapy for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction $< 45\%$ who are stabilised after a recent heart failure decompensation event requiring admission and/or IV diuretic therapy.

<https://tinyurl.com/yt7zt644>

MBS news

From 1 January 2022, a new item (63399) was listed on the MBS for cardiac MRI to assist in diagnosing myocarditis associated with mRNA COVID-19 vaccination. The item will be available for use until 30 June 2022.

<https://tinyurl.com/567by4m>

From 1 January 2022, changes were made to five MBS items for Cardiac Services T8 items. These changes will ensure consistent Medicare rebates for patients and will clarify claiming requirements for providers.

<https://tinyurl.com/mry6b4d4>

From 1 March 2022, MBS item 38276 will be amended to expand patient access to left atrial appendage closure procedure for patients with non-valvular atrial fibrillation for stroke prevention. Patients with an absolute and permanent contraindication to oral anticoagulation therapy documented by a medical practitioner who has not been involved in the decision to provide the surgical procedure will now be eligible for Medicare rebates.

<https://tinyurl.com/bdhh5p>

From 1 March 2022, one new MBS item (38514) will be introduced for TAVI for patients with symptomatic severe aortic stenosis at intermediate risk for open surgical aortic replacement, device agnostic. One MBS item (38495) will also be amended for TAVI for patients with symptomatic severe aortic stenosis at high risk for open surgical aortic replacement, device agnostic.

<https://tinyurl.com/56dm9ja6>

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at least 2 CVD risk factors.^{1,2}



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CRESTOR (rosuvastatin [as calcium]) 5, 10, 20, 40 mg tablet blister. **Indications:** Use as adjunct to diet when diet/exercise alone is inadequate. Use to prevent major CV events in men ≥ 50 yrs and women ≥ 60 yrs with ≥ 2 CV risk factors. Use to treat hypercholesterolaemia (HCL) (incl. familial); identify/treat secondary causes prior to initiating. **Dosage and Administration:** initiate with 5 or 10 mg daily in statin naive or switched patients; adjust after 4 weeks. Recommended max is 20 mg/d except for max 40 mg/d in patients with high CV risk e.g. familial HCL who will be monitored/under specialist. For Asian pop.: initiate with 5 mg/d; don't use 40 mg. Limit dose to 5 mg/d with ciclosporin and 10 mg/d with gemfibrozil. Not recommended in paediatrics. Initiate with 5 mg/d in severe hepatic or severe renal impairment; max 10 mg/d. Consider genetic polymorphisms. See approved PI. **Contraindications:** Hypersensitivity to active or excipients. Acute liver disease. Pregnancy; breastfeeding; women of childbearing potential unless using contraceptives. Fusidic acid. 40 mg if pre-disposing factors for myopathy/rhabdomyolysis. See Approved PI. **Precautions:** Perform liver function tests at initiation and periodically; monitor serum transaminases and reduce/discontinue dose if >3 times ULN; substantial alcohol consumption and/or history of liver disease. Caution if pre-disposed to myopathy or with concomitant products (see Interactions); temporarily discontinue if elevated CK, in acute illness suggestive of myopathy or renal failure secondary to rhabdomyolysis. HbA1c and serum glucose increase. Caution concomitant drugs that decrease endogenous steroids. Prevention of CV events in patients with low CV risk factors not established. Use of CRP testing in prevention of CV effects. Discontinue if interstitial lung disease developed. Caution in Asian subjects. Severe renal and hepatic insufficiency. Effects on laboratory tests. Pregnancy (Cat. D) and breastfeeding. See Approved PI. **Interactions:** OATP1B1 and BCRP inhibitors may increase plasma conc. and risk of myopathy. Dose adjustments required with multiple concomitant drugs. Antacids. Discontinue during treatment with fusidic acid. Warfarin and Vit K antagonists, assess and monitor INR. Gemfibrozil, fenofibrates, fibric acid derivatives; ciclosporin; protease inhibitors with ritonavir. See approved PI. **Adverse Effects:** Common: dizziness; diabetes mellitus; constipation; nausea; abdominal pain; myalgia; asthenia; headache. Rare: myopathy; rhabdomyolysis. See approved PI. [mPI Version 3.0].

CVD: cardiovascular disease; CV: cardiovascular; RRR: relative risk reduction. **References:** 1. CRESTOR Approved Product Information. 2. Ridker P *et al. N Engl J Med* 2008;359:2195-2207. CRESTOR is a trademark of A. Menarini Australia Pty Ltd in Australia and New Zealand. Menarini Australia Pty Ltd, Level 8/67 Albert Ave, Chatswood NSW 2067. Copyright A. Menarini Australia Pty Ltd 2021. 1800 644 542. ABN 62 116 935 758. Prepared: June 2021. CRE-AU-1553. CRES0126/EMBC



News in Brief

COVID-19 vaccination-associated myocarditis in adolescents

This US retrospective multicentre study characterised COVID-19 vaccination-associated myocarditis in 63 paediatric patients (mean age 15.6 years; 92% male). All patients received messenger RNA vaccine and all but one presented after the second dose. Four patients experienced significant dysrhythmia. Mild left ventricular dysfunction was observed with echocardiography in 14% of patients, which resolved on discharge, and 88% met diagnostic cardiovascular magnetic resonance Lake Louise criteria for myocarditis. Myocardial injury, late cardiovascular magnetic resonance gadolinium enhancement, was more prevalent than multisystem inflammatory syndrome in children. There were no deaths and no patients required inotropic, mechanical, or circulatory support. Follow-up data from 86% of patients after a mean of 35 days revealed complete resolution of symptoms, arrhythmias, and dysfunction.

<https://tinyurl.com/2p9bxz5u>

Myocarditis after BNT162b2 mRNA vaccine against COVID-19 in Israel

This study determined the prevalence of myocarditis after receipt of the mRNA COVID-19 vaccine BNT162b2 in Israel. Between 20 Dec 2020 and 31 May 2021, 142 individuals developed myocarditis after receipt of the BNT162b2 vaccine (136 diagnoses were definitive or probable). 95% of cases were mild but 1 was fatal. The overall risk difference between the first and second doses was 1.76 per 100,000 persons, with the greatest increase seen in males aged 16–19 years (13.73 per 100,000 persons). Compared with unvaccinated individuals, the rate ratio 30 days after the second vaccine dose in fully vaccinated recipients was 2.35 (95% CI 1.10–5.02).

<https://tinyurl.com/2p8jv73z>

Comprehensive management of cardiovascular risk factors for adults with type 2 diabetes: A scientific statement from the American Heart Association

A comprehensive approach is recommended for management of cardiovascular risk factors among patients with type 2 diabetes, according to this AHA scientific statement. This statement focuses on (1) newer antihyperglycaemic agents for improving glycaemic control and reducing cardiovascular events; (2) the impact of blood pressure control on cardiovascular events; and (3) the role of newer lipid-lowering therapies in comprehensive cardiovascular risk management. The statement addresses the importance of lifestyle interventions, pharmacological therapy, and surgical interventions to reduce obesity and metabolic syndrome, important precursors of prediabetes, diabetes, and comorbid cardiovascular disease. In addition to clinical care and treatment, social determinants of health must be considered.

<https://tinyurl.com/2cxe8tp2>

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COVID-19 Resources for Cardiologists

CSANZ <https://tinyurl.com/y3xp2729>

ACC <https://tinyurl.com/y68aud3a>

ESC <https://tinyurl.com/wn3fst>

Conferences, Workshops and CPD

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

ACRA <https://tinyurl.com/y4yj8xb5>

CSANZ <https://tinyurl.com/3mwt5tr>

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/y2khytptz>

AHA <https://tinyurl.com/zajc9a7>

ESC Congresses and Events <https://tinyurl.com/y6ko68yf>

ESC Education <https://tinyurl.com/y3zkip3o>

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/hxrsrv6>

Interventional Cardiology Research Review

with Conjoint Professor Craig Juergens

<http://tinyurl.com/h3h3wcp>

AHA 2021 Conference Review

<https://tinyurl.com/bd7crb73>

Lipids Year in Review 2021

<https://tinyurl.com/2p8uffmt>

Study Review – Thromboembolism, bleeding, and vascular death in nonvalvular AF

<https://tinyurl.com/yckv687t>

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