POSITION STATEMENT ON THE MANAGEMENT OF CARDIAC ELECTROPHYSIOLOGY AND CARDIAC IMPLANTABLE ELECTRONIC DEVICES IN AUSTRALIA DURING THE COVID-19 PANDEMIC: A LIVING DOCUMENT

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The recommendations of this document are current as of Thursday March 26, 2020.
INTRODUCTION

On December 19, an outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) marked the beginning of a pandemic that has had a major impact on health care systems around the world. SARS-CoV-2 also known as COVID-19 causes a pneumonic respiratory illness, with the potential for severe cardiovascular damage. Its high infectivity rate has led to rapid escalation of affected cases around the world. It demonstrates a higher mortality rate amongst patients with pre-existing illness, in particular, those with cardiovascular disease. This has prompted a rapid evaluation of routine cardiac electrophysiology (EP) and Cardiac Implantable Electronic Devices (CIED) services within Australia. Major international societies (Heart Rhythm Society, British Heart Rhythm Society), have emergently released guidelines as live documents for the provision of such services.

In response to this pandemic, the Cardiac Society of Australia and New Zealand (CSANZ) Board has summoned the Heart Rhythm Council to rapidly produce a live document providing guidance to its members for the practice of EP and CIED services in Australia. This live document takes into account published grey papers from international societies, and advice from key opinion leaders within Australia and overseas, with frequent updates to adapt to the evolving pandemic and its impact on the Australian health system. The guidelines provide a framework for implementing services during the pandemic. It is noted that the practice of EP and CIED management in Australia is varied amongst public and private hospitals, regional and remote areas, and in outreach clinics. The application of these recommendations will therefore need to be tailored to local models of service delivery.

In response to the CSANZ board request, the Chair of the Heart Rhythm Council has summoned the formation of the Heart Rhythm Council COVID-19 Pandemic working group. The group will be formed by the authors listed in this document whose responsibility will be to contribute to the original source document and provide frequent updates in four domains:

1. **Implementing a Framework for altered services:** Rukshen Weerasoriya, Stewart Healey, Andrew McGavigan.
2. **Monitoring and follow up of patients with CIED:** Justin Mariani, Gareth Wynn, Brad Wilsmore, Paul Gould, Paul Weatherley.
3. **Ambulatory monitoring:** Jonathan Lipton, Rajiv Mahajan, Rajeev Pathak.
4. **EP and CIED procedural considerations:** Jonathan Kalman, Prashanthan Sanders, Stuart Thomas, Haris Haqqani.

One further domain to be established is Paediatric, Adult Congenital Heart Disease management which will be released in a subsequent update.

The Heart Rhythm Council of NZ was consulted and they have indicated that a separate consensus document will be generated specific to practice in NZ.
DOMAIN 1: IMPLEMENTING A FRAMEWORK FOR ALTERED SERVICES

The COVID-19 pandemic requires rapid re-evaluation of EP and CIED services, as outlined below:

1. We strongly recommend that all physicians involved with the provision of services related to EP and CIED management hold a forum within their network to discuss and implement these guidelines.

2. Each of the networks should work closely with their hospital or network’s established COVID-19 Taskforce group ideally comprising of one or more of: cardiology department heads, EP leads, CIED program heads, infectious disease specialists, population health physicians, emergency department physicians, nurses and allied health staff, industry partners and hospital administration to formulate a plan for ongoing management of EP and CIED procedures and clinics, using these guidelines. The group should meet at weekly intervals to ensure maintenance of appropriateness criteria, urgency and alignment of practices with the local outbreak response phase.

3. We recognise that such infrastructure may not exist in private practices, but advise that a framework be established within one or more partners within the group, and the host hospital where consultation and procedures are performed. Where not possible or practical, such as in the instance of solo practitioners, we advise adherence to CSANZ recommendations.

4. Tele-conferencing is recommended to avoid cross infection of the leadership group.

5. We recommend nomination of a group leader within the network who will co-ordinate and implement the action plan and an assistant lead who should monitor national and global trends closely, and adapt to local and national recommendations.

6. We recommend nomination of a triaging lead physician (1 EP, 1 CIED program) who works with a triage nurse or allied health staff member, and the head of department to review clinical need and urgency of each elective and inpatient procedure, and maintain consistency in line with these published recommendations.

7. We recommend immediate and indefinite deferment of all non-urgent elective cardiac electrophysiology and CIED implant procedures to preserve resources for urgent cases and allow catheterisation labs time to prepare for the use of personnel protection equipment (PPE) and to practice enhanced cleaning procedures.

8. All outpatient consultations should be altered to telephone or teleconference as soon as possible to reduce social interaction of vulnerable patients and/or vulnerable physicians. If feasible, outpatient services should remain to support general practices and emergency department (ED) referrals.

9. Electronic medical records of arrhythmia patients will need to be available in a format to be shared rapidly with ED physicians, intensive care physicians, general practitioners, and the rural medical workforce.

10. We recommend that weekly review of upcoming schedule of clinics and procedures with the aim of identifying patients that:
   a. can be safely rescheduled for a follow up or a procedure after >3 months;
   b. can be invited to a virtual visit via teleconference;
   c. must be seen face-to-face (strongly discouraged);
DOMAIN 2: MONITORING AND FOLLOW UP OF PATIENTS WITH CIED

Management of patients requiring follow up for device therapy presents a number of particular challenges during the COVID-19 pandemic. Namely:

- Frequent presence of high-risk comorbid conditions including advanced age;
- Direct physical contact required for in-person device checks;
- High risk of significant adverse impact of delayed or missed review appointments in selected patients.

Remote monitoring is a powerful tool for the management of patients with implanted devices. Unfortunately, although there is high penetrance of remote monitoring in recently implanted privately insured patients, outside of this group there are far fewer patients with remote monitored devices.

Although additional monitors can be purchased, there is a significant cost (approximately $400 per patient) associated with this as well as a limited stock of available monitors. In addition, not all implant devices currently in active use in Australia are compatible with home monitoring.

Although COVID-19 is spread primarily through respiratory droplets and close contact with an infected person, the virus may also be spread by contact with contaminated surfaces. Each of the networks should consult with their hospital’s infection control or COVID-19 task force regarding recommended cleaning. Practices operating out of private consulting rooms should follow the guidelines of their nearest academic hospital who have as established infection control service.

The aim of these recommendations is to reduce patient, personnel and programmer exposure to COVID-19. Due to the rising community transmission of COVID-19, asymptomatic carriage and asymptomatic incubation period and post illness viral shedding, it is feasible that every patient will be perceived as equivalent risk of transmitting COVID-19. These guidelines may change rapidly, in line with rising community prevalence.

In patients with CIED:

1. We recommend that remote monitoring be utilised as much as practically feasible, to avoid in-office visits to hospitals, clinics and practices.
   a. For patients who are not currently enrolled in remote monitoring, new enrolment should be strongly considered.
   b. In new device implants, home monitoring should be instituted, where feasible.
   c. For patients already enrolled in remote monitoring and have active ongoing conditions, drug therapies, or planned interventions, or follow up after catheter ablation interventions that require in-person evaluation, we recommend that the treating physician replace routine office visits with a remote visit (Skype, Zoom, telephone). A number of billing codes have been released by the Federal Government to help facilitate this arrangement.

2. We discourage routine in-hospital and in-person device interrogations in stable patients, with chronic indications for device therapy, and sufficient calculated battery longevity (>3 months).
   a. In patients with implanted cardiac defibrillators in whom there is a need to confirm whether therapies (anti-tachycardia pacing/shock) have been delivered, home monitoring and/or manual transmission should be the preferred modality for confirmation. For each patient that has experienced defibrillator therapy, the treating physician should undertake an individualised risk assessment and then decide how best to manage their patient. Options might include telehealth review, clinic review or rarely admission;
   b. In patients with implanted cardiac devices with suspected lead malfunction or battery issues, the treating physician should undertake an individualised risk assessment and then
decide how best to manage their patient, options might include, telehealth review, clinic review or rarely admission;

During in person device checks we encourage the use of wireless communication technology by CIED allied staff to maintain a safe distance (>1.5 metres). In addition, we encourage limitation of the number of people present during the device check (i.e. only patient, clinician and CIED allied health staff). To minimise the duration of contact also during the visit for device check we suggest that device data is downloaded and saved and reviewed away from the patient.

Where feasible, remote monitoring and/or manual transmissions should be used in stable patients, for routine follow up. A number of such facilities exist (e.g. Merlin on-demand [Abbott Medical]; Carelink Express [Medtronic]).

The immediate post implant follow up should be done remotely where possible with scar review via photo, or live audio-visual technology.

During the pandemic period, we strongly recommend that all patients undergoing new device implantation are, wherever possible, provided with remote monitoring devices.

In patients with magnetic resonance imaging (MRI)-conditional devices requiring urgent MRI scanning we recommend use of automatic reprogramming functions where available.

Perioperative re-programming of CIEDs is only necessary for:¹,²
a. surgery within 15 cm radius of the CIED (can);
   b. procedures above the iliac crest and patient positioning would prevent easy securing of a magnet if required (pacemaker inhibition induced for pacemakers and all non-pacing dependent defibrillators);
   c. pacing dependent ICD patients for procedures above the iliac crest;

For patients in whom in-hospital or ambulatory in person interrogation is absolutely critical and/or necessary, we recommend screening for symptoms or history of exposure to COVID-19. It is very likely that universal PPE will be implemented in time given the rising rate of community transmission of COVID-19. Wherever possible, in-person device interrogation should be delayed until the patient is deemed no longer infective by the appropriate treating team/according to local or national protocols.

In patients in whom COVID-19 is confirmed or suspected, strict protocol of PPE should be followed, using the hospital approved protocols;

   aa. we recommend that 1-3 designated CIED allied health staff undergo comprehensive PPE training and re-training to ensure competency in PPE use;
   bb. we recommend that a strict roster of staff be maintained for in patient or in clinic interrogations to minimise all CIED allied health staff being exposed simultaneously and to conserve intellectual resources within the network – this may mean weekly or biweekly coverage by one staff member, with backup CIED allied health staff 1 and 2, if needed;

In patients with respiratory symptoms in whom COVID-19 has been excluded, standard contact and droplet precautions, as recommended hospital approved protocols should be followed;

In patients without any respiratory symptoms or risk factors for COVID 19 exposure, avoid direct patient contact and maintain commonly recommended social isolation practices (e.g. 1.5 meter distance, avoiding an enclosed space) should be followed;

We recommend that each department should quarantine a single set of programmers for in person evaluation of all patients during the pandemic. These programmers should be stored in a separate area of the cardiac unit. The programmer is to be cleaned with disinfectants approved by hospital protocols to have activity against COVID-19 before and after each interrogation and at the beginning and the end of the day. Consider a transesophageal probe cover for the interrogation wand, changed between patients as well, given this is the specific interface.
e. We recommend that staff involved in care of patients with electrophysiology and pacing services implanted devices wear cardiac surgical scrubs.

f. Given the anticipated burden of COVID-19 on the health system and the heightened vulnerability of health care workers, we recommend that where feasible, network consider that allied health staff involved in the delivery of EP and CIED services be divided into ‘lab based’ vs ‘clinic based’ teams, and be designated different work spaces, to avoid being in the same working region. Clinic based teams be available for education and support of patients, and work closely with physicians and arrhythmia nurses to avoid hospitalisations and in person visits, where feasible.

9. Where necessary, Emergency Departments and hospital wards should have access to on demand device monitoring systems that are available (Medtronic Carelink Express and Abbott Merlin On Demand). Where indicated, device monitoring for patients attending ED should be performed using available on demand systems. In all other situations, the patient’s cardiologist or the on call cardiologist should be contacted. We recommend that device company representatives are not to be contacted first line.

10. We recommend that company representatives minimise their presence in device implants and clinics, as they often not adequately trained in PPE use, infection control practices, and travel between multiple centers, with high risk of potential exposure and transmission. If deemed necessary for a procedure, we recommend that each center have a designated representative, where feasible, to assist with implants. The number of personnel during an implant should be minimised.
**DOMAIN 3: AMBULATORY MONITORING**

Ambulatory monitoring is of variable diagnostic yield, and may be avoided during the COVID-19 pandemic as routine elective procedures are being deferred (see below).

1. We **discourage the routine use of ambulatory Holter monitors or exercise stress tests** (which involve direct patient interaction), for the screening, surveillance, ongoing management and/or follow up of patients with suspected or confirmed cardiac arrhythmias.
   a. where the clinical indication for the aforementioned non-invasive tests is weak, we recommend that such testing be deferred for >3 months, or until such time the pandemic has passed;
   b. in low risk patients (e.g. those with undiagnosed, infrequent palpitations and a structurally normal heart), smartphone or smartwatch acquired ECGs may be considered (e.g. AliveCor Kardia). Although small studies and anecdotal reports suggest that these may be useful, large scale randomised controlled data is lacking. The use of heart rate monitors (e.g. Fitbit, Garmin watch) are unlikely to be useful in this setting, and is discouraged.
   c. when clinically necessary, we recommend the use of ambulatory monitors that can be mailed out to patients (e.g. Heartbug, Ziopatch).
2. In the rare instance that ambulatory Holter monitoring and/or stress testing is the ONLY option for investigation of a patient, advice listed in Item 8 of Domain 1 should be followed. Equipment must undergo a thorough clean before and after each use using hospital approved disinfectants that are active against COVID-19.
DOMAIN 4: ELECTROPHYSIOLOGY AND CIED PROCEDURAL CONSIDERATIONS

Given the potential for rapid dissemination of COVID-19 throughout the health system, we recommend that all non-critical elective electrophysiology and CIED procedures be deferred indefinitely until the COVID-19 crisis has ended, with the exception of high priority cases as detailed below. The rationale for this is that an elective procedure in an unsuspected COVID-19 positive patient carries the potential infectivity of physicians, nursing, anesthetic and allied health staff and fellow inpatients for rapid transmission of COVID-19. Current inpatient procedures should be performed as rapidly as possible to facilitate discharge. If inpatient procedures are not deemed critically necessary and can be deferred for a minimum of 3 months, early discharge is recommended. More frequent telehealth follow up (e.g. weekly or monthly) is recommended to ensure that clinical stability is maintained in such patients, so to avoid hospital re-admissions.

Given the scarcity of resources and the anticipated burden of the COVID 19 pandemic, it is unlikely that any of the standard elective EP / CIED procedures will able to performed in most Australian hospitals.

Exceptions to this would be for the following procedures:

1. Pacemaker insertion for those with asystolic pauses or advanced AV block.
2. Defibrillator insertion for survivors of a cardiac arrest.
3. Generator replacement for pacing dependent patients or those with previous appropriate defibrillator therapies who are at end of life (EOL).
4. Catheter ablation for medically-refractory, ventricular arrhythmia storm, on an exceptional basis, with the criteria listed below, as determined by the consensus of experts at the specialist centre for the management of ventricular arrhythmias.*
5. Transvenous lead extraction (TLE) on an exceptional basis as determined by the consensus of experts at the specialist accredited centres, taking into account the resource use implications and ancillary support teams (e.g. cardiac surgical backup, anaesthesia, ICU) required to carry out such a procedure, and its potential attendant complications.

*Ventricular arrhythmia storm includes sustained monomorphic VT or PVC induced VF. Storm defined as sustained VT lasting >12 hours or ≥3 episodes of VT within 24 hours. Decisions regarding ablation of ventricular arrhythmia storm need to be taken in the context of the patient’s overall mortality risk, the large personnel and equipment burden on the health care system during such procedures and scarcity resources available, and the risk of managing potential complications of the procedure. In patients with severe left ventricular dysfunction (ejection fraction ≤35%), this should be discouraged. These patients may require a significant period in ICU and this is to be avoided. We recommend that such ablation procedures be discussed in a multi-disciplinary setting with the treating physician, an adjudicating electrophysiology colleague, head of department, anesthetic and intensive care staff, before proceeding. Approval to be obtain within this group before proceeding.

The Heart Rhythm Council COVID-19 Pandemic working group does not agree with the National cabinet recommendations to continue semi urgent category 2 and 3 elective procedures pertaining to EP or CIED to continue at private hospitals to 11.59pm on April 1, 2020.
DOMAIN 5: ARRHYTHMIC IMPLICATIONS OF COVID-19

The intention of this domain is to provide updated information source on the arrhythmic implications of COVID-19.

Introduction

Palpitations and chest tightness are uncommon but recognised presenting symptoms of SARS-CoV-2 (COVID-19) infection. Increasing age and the presence of multiple medical comorbidities are associated with more severe infection and increased mortality. In at least one series arrhythmias were reported in 16.7% of hospitalised patients and was more common in those patients managed in the intensive care unit. Myocardial injury with raised troponin levels may be identified in hospitalised patients and is a marker of increased mortality. Atrial and or ventricular arrhythmias may be due to exacerbation of pre-existing arrhythmias with underlying cardiovascular disease in the setting of acute respiratory infection, or due primarily to myocarditis, hypoxaemia, inflammation, inotropes, and/or side effects of specific anti-viral therapies (commonly QT prolongation). Details on arrhythmias specific to or unique to SARS-CoV-2 infection are lacking. Heart rhythm specialists may be asked to assist in the management of arrhythmias or in the monitoring of empirical drug therapy regimens.

Detail

Whilst the most common presenting clinical symptoms of SARS-CoV-2 infection are fever, cough and respiratory symptoms some patients in China first presented with palpitations and chest tightness. The reports of arrhythmias with SARS-CoV-2 infection are limited but appear common. Whilst most patients have a mild infection 10-20% may develop severe infection and a proportion of these will require management in an intensive care unit.

In Influenza infection, cardiovascular complications include myocarditis, acute myocardial infarction (plaque rupture secondary to viral inflammation) and exacerbation of heart failure. Previous Coronavirus infections have also been associated with cardiovascular complications. The risk of adverse outcomes and the severity of adverse outcomes is increased by pre-existing cardiovascular disease. SARS has previously been associated with hypotension, tachycardia, bradycardia, atrial and ventricular arrhythmias. ECG changes and a troponin rise may indicate myocarditis. Myocarditis may recover with supportive therapy and arrhythmias may be transient.

With SARS-CoV-2, older age and the presence of underlying medical conditions appears to increase complications and mortality.

The Italian experience shows that of all deaths only 1.2% occurred in patients with no co-morbidities and 48.6% of deceased patients had three or more co-morbidities (COVID-19 Surveillance group). This may relate to reduced immunity and it has been noted that the SARS-CoV-2 virus binds to alveolar and myocardial cells via the ACE2 receptor. Myocardial injury with troponin rise may be seen in up to 17% of hospitalised patients and is a risk factor for mortality. The mechanisms of cardiac injury include myocarditis, hypoxaemia, and cytokine storm. Myocarditis may be associated with ECG changes and arrhythmias but detailed observations on arrhythmias specific to SARS-CoV-2 are limited.

The large series published from the Wuhan infection epicentre in China by Wang and colleagues shows the severity of SARS-CoV-2. In this series, the complications included acute cardiac injury 7.2%, shock 8.7%, arrhythmias 16.7% and overall 26% of hospitalised patients required ICU care. Details on specific arrhythmias were not provided but were more common in ICU than non-ICU patients. Other smaller studies have demonstrated similar observations with the development of cardiomyopathy in 1/3 of patients admitted to ICU.
Potential drug therapies for SARS-CoV-2 may exacerbate cardiac arrhythmias. Hydroxychloroquine has been touted as a possible agent which might reduce the severity of or prevent infection.\textsuperscript{10} Hydroxychloroquine (Plaquenil) is a chloroquine derivative and like all the related drugs in this group may cause QRS widening and QT prolongation. However, it is safer to use than chloroquine. Cases of Torsades de pointes secondary to this drug are published. The half-life of the drug is very long and the risk is related to either over-dosage acutely or high dose long term usage. Hydroxychloroquine is being used in combination with the antimicrobial azithromycin in clinical trials and shown to reduce viral load.\textsuperscript{11} This drug has anti-inflammatory effects. This antibiotic may cause Long QT and Torsade de Pointes. Case reports exist for potentiation of long QT in patients with hypokalaemia and co-administration of other QT prolonging drugs e.g. chloroquine.\textsuperscript{12}

No doubt other therapies are being assessed and include Interferon-alpha and the specific anti-viral Remdesivir.\textsuperscript{9} The cardiovascular side effects of the latter are currently unknown.
References

1. Crossley GH, Poole JE, Rozner MA, Asirvatham SJ, Cheng A, Chung MK, Ferguson TB, Jr., Gallagher JD, Gold MR, Hoyt RH, Irefin S, Kusumoto FM, Moorman LPThompson A. The Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) Expert Consensus Statement on the perioperative management of patients with implantable defibrillators, pacemakers and arrhythmia monitors: facilities and patient management: executive summary this document was developed as a joint project with the American Society of Anesthesiologists (ASA), and in collaboration with the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS). Heart Rhythm. 2011;8:e1-18.


