Health Policy Advisory Committee on Technology

Technology Brief

Cardiovascular Magnetic Resonance (CMR) for the diagnosis of coronary heart disease

February 2013

HealthPACT
emerging health technology
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This brief was prepared by Dr. Vicki Foerster, Ben Hoggan and Dr.Merrick Edgar-Hughes, Deanne Forel, StefGurgaczcf from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).
Technology, Company and Licensing

Register ID       WP 140
Technology name  Cardiovascular Magnetic Resonance (CMR) for the diagnosis of Coronary Heart Disease
Patient indication For the diagnosis of coronary heart disease (CHD) as an alternative to other imaging modalities such as non-invasive single-photon emission computed tomography (SPECT) and invasive X-ray angiography.

Description of the technology

Single-photon emission computed tomography (SPECT) is a common test for the assessment of myocardial ischaemia in patients with suspected coronary heart disease (CHD). However, SPECT has limitations, such as variable diagnostic accuracy and the use of ionising radiation. Cardiovascular magnetic resonance (CMR) is a potential alternative due to its high spatial resolution, absence of ionising radiation, and ability to assess multiple aspects of pathology in a single examination.

CMR is a medical imaging technology for the non-invasive assessment of the function and structure of the cardiovascular system. It is derived from, and based on, the same basic principles as magnetic resonance imaging (MRI) but with optimisation for use in the cardiovascular system. CMR has been employed at specialised centres for several years to assess cardiac anatomy (e.g. myocardial masses, ventricular anatomy, infarction, necrosis and cardiac pulse sequences), but CHD is a new indication for the use of this technology in diagnosis.

Company or developer

The Australian Register of Therapeutic Goods (ARTG) lists three manufacturers of SPECT systems and five manufacturers of full-body MRI systems that may be able to be used for CMR (Table 1).
Table 1 A selection of SPECT and MRI systems listed on the Australian Register of Therapeutic Goods

<table>
<thead>
<tr>
<th>Company</th>
<th>ARTG No and Class</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SPECT</strong></td>
<td></td>
</tr>
<tr>
<td>Medical Imaging Services</td>
<td>183937, IIb</td>
</tr>
<tr>
<td>Philips Electronics Australia Ltd</td>
<td>117440, IIb</td>
</tr>
<tr>
<td>Siemens Ltd</td>
<td>123883, IIb</td>
</tr>
<tr>
<td><strong>MRI (full-body)</strong></td>
<td></td>
</tr>
<tr>
<td>Emergo Asia Pacific Pty Ltd</td>
<td>136622, IIa</td>
</tr>
<tr>
<td>GE Healthcare Australia Pty Ltd</td>
<td>108415, IIb</td>
</tr>
<tr>
<td></td>
<td>135096, IIb</td>
</tr>
<tr>
<td></td>
<td>169744, IIa</td>
</tr>
<tr>
<td></td>
<td>169036, IIa</td>
</tr>
<tr>
<td>Philips Electronics Australia Ltd</td>
<td>98887, IIb</td>
</tr>
<tr>
<td>Siemens Ltd</td>
<td>98319, IIb</td>
</tr>
<tr>
<td></td>
<td>98485, IIa</td>
</tr>
<tr>
<td></td>
<td>144221, IIa</td>
</tr>
<tr>
<td></td>
<td>154128, IIa</td>
</tr>
<tr>
<td>Toshiba Australia Pty Ltd</td>
<td>126911, IIa</td>
</tr>
</tbody>
</table>

ARTG = Australian Register of Therapeutic Goods; MRI = magnetic resonance imaging; SPECT= single-photon emission computed tomography.

**Reason for assessment**

A device optimised for use in the cardiovascular system that may provide non-invasive alternative for the diagnosis of coronary heart disease.

**Stage of development in Australia**

- [ ] Yet to emerge
- [x] Experimental
- [ ] Established but changed indication or modification of technique
- [ ] Investigational
- [ ] Should be taken out of use
- [ ] Nearly established

**Licensing, reimbursement and other approval**

Table 1 contains information regarding the ARTG numbers associated with the both SPECT and MRI systems that may to be able to be used for CMR.

**Australian Therapeutic Goods Administration approval**

- [x] Yes
- [ ] No
- [ ] Not applicable

**ARTG number(s)** – see Table 1 for details

**Technology type** Procedure

**Technology use** Diagnostic
**Patient Indication and Setting**

**Disease description and associated mortality and morbidity**

CHD is the most common form of cardiovascular disease. In a trend seen clearly for males (less so for females), overall CHD prevalence is highest in the lowest socioeconomic group and lowest in the highest socioeconomic group. For Indigenous Australians, the prevalence is twice that of non-Indigenous Australians when adjusted for age differences.\(^1\)

In 2007–08 there were around 160,000 hospitalisations (episodes of care) with a principal diagnosis of CHD, comprising two per cent of all hospitalisations; of these, angina accounted for 44 per cent and acute myocardial infarction (MI) for 35 per cent. A declining trend has been seen over the past two decades, from 867 hospitalisations per 100,000 population in 1993–94 to 709 per 100,000 in 2007–08.\(^1\) Similar data for New Zealand were not readily available.

**Number of patients**

The 2007–08 National Health Survey reported that about three per cent of the Australian population had experienced CHD (~685,000 people), and of those about half (353,000) had experienced angina.\(^1\)

Major coronary events occurred in approximately 50,000 Australian adults (62% male) in 2007–08, or at a rate of about 135 per day; nearly 40 per cent were fatal. The prevalence of CHD is higher among males than females in all age groups over the age of 35 years and increases markedly with age; for example, seven per cent of Australians aged 55–64 years were estimated to have CHD, and this increases to 24 per cent for those aged 85 years and over.\(^1\)

**Specialities** Cardiology / Radiology

**Technology setting** Specialist Hospital / General Hospital / Ambulatory Care

**Impact**

**Alternative and/or complementary technology**

From the evidence reviewed for this report it appears that SPECT is the primary alternative non-invasive imaging technique for assessing the condition of coronary arteries. It is therefore possible that CMR will replace SPECT if its performance is shown to be superior, particularly as CMR avoids the use of ionising radiation.

**Current technology**

In addition to CMR and SPECT, non-invasive investigations for CHD include exercise/stress electrocardiography, echocardiography and computer tomography coronary angiography (CTCA). The reference standard is traditional X-ray angiography, which is invasive. CTCA is an
emerging alternative for symptomatic patients with low to intermediate pre-test probability of CAD.

**Diffusion of technology in Australia**

Cardiac MRI is widely available in Australia. In Western Australia, the three major teaching hospitals have separate in house CMR services. Additionally there are at least two private provided conducting this service in Perth. In Auckland, the three tertiary teaching hospitals have in house CMR services. The Alfred Hospital in Victoria currently uses MR to conduct left ventricular function studies. All of the capital cities in Australia, and some major regional centres have varying levels of CMR services available to them locally (personal communication WA Health).

**International utilisation**

<table>
<thead>
<tr>
<th>Country</th>
<th>Trials underway or completed(for CHD specifically)</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>√</td>
<td>Possibly but extent is unclear</td>
<td></td>
</tr>
<tr>
<td>Hungary</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

* For cardiac indications other than diagnosis of CHD

**Cost infrastructure and economic consequences**

MRI devices are expensive to purchase and operate – particularly 3-Tesla machines that can cost in the order of $4 million. However, CMR can be conducted using 1.5T machines which cost approximately $1.2- 2 million. Additional expenses include site preparation for installation, ongoing service contracts, staff costs, staff training, physician fees, contrast media, disposables etc. Currently, MRI machines are mainly installed at large referral hospitals.

The utilisation of MRI in Australia is managed through requestor, provider and item level restrictions, put in place by the Australian Federal Government Department of Health and Ageing. In 2012, under the Diagnostic Imaging Review Reform Package, the number of full and partial Medicare-eligible MRI units was increased to 341 machines Australia-wide, including the provision of up to 30 full Medicare-eligible MRI units in regional locations.
Use of CMR for a common disorder, CHD, would have significant implications for device use and wait times, particularly given the limitations in MRI licensing.

**Ethical, cultural or religious considerations**
No specific considerations were identified.

**Evidence and Policy**

**Safety and effectiveness**
Clinical evidence included in this report comes from a large prospective comparative trial (level II diagnostic accuracy study) conducted in the UK, and a large prospective multivendor trial (level III-1 diagnostic accuracy study) conducted in multiple centres across Europe and the US.

**Greenwood et al, CE-MARC study**
The Clinical Evaluation of Magnetic Resonance imaging in Coronary heart disease (CE-MARC) study was designed to establish the diagnostic accuracy of CMR in a large real-world population, and to test the hypothesis that CMR yields higher diagnostic performance than SPECT, using X-ray coronary angiography as the reference standard.

Performed between 2006 and 2009, this level II diagnostic accuracy study included 752 adults with possible CHD. Consecutive patients who presented with suspected angina pectoris and at least one cardiovascular risk factor, and who met study inclusion criteria (only 752 of 4065 patients were assessed for eligibility [18%]), were scheduled for CMR (1.5 Tesla Philips CV scanner), SPECT (cardiac gamma camera, MEDISO Cardio-C), and X-ray coronary angiography. For the angiography, clinically significant CHD was defined as ≥ 70 per cent stenosis of a first order coronary artery of diameter ≥ 2 mm, or left main stem stenosis ≥ 50 per cent.

Patients (mean age 60 years, 63% men, 95% Caucasian) were randomised to receive CMR or SPECT first, followed by angiography, once both CMR and SPECT had been performed. CMR consisted of rest and adenosine stress perfusion, cine imaging, late gadolinium enhancement and 3D MR angiography. SPECT (gated adenosine stress and rest) used $^{99m}$Tc-tetrofosmin. CMR and SPECT were performed a mean of seven days apart and angiography a mean of 21 days later. SPECT, CMR and X-ray coronary angiogram results were analysed in accordance with international criteria by masked, paired readers with at least 10 years of experience with the modality.

The primary outcome was diagnostic accuracy of CMR (sensitivity, specificity, positive predictive value [PPV] and negative predictive value [NPV]). The primary outcome analysis included patients with complete data from both CMR and X-ray coronary angiography with no interim cardiovascular events. The main secondary outcome was a comparison of multi-
parametric CMR and SPECT with X-ray angiography as the reference. An additional analysis compared only the equivalent components of the CMR protocol with SPECT. The study was funded by the British Heart Foundation and the authors declared no conflicts of interest.

**Safety**

Ten patients had 11 serious adverse events, all related to X-ray coronary angiography: eight vascular access site complications (haematoma), one minor neurological event, one ventricular arrhythmia and one acute event needing percutaneous coronary intervention.

**Effectiveness**

For the primary outcome measure (CMR versus X-ray coronary angiography) the following results were obtained:

- Sensitivity 86.5% (95% CI [81.8, 90.1])
- Specificity 83.4% (95% CI [79.5, 86.7])
- PPV 77.2% (95% CI [72.1, 81.6])
- NPV 90.5% (95% CI [87.1, 93.0]).

Table 2 displays results for the secondary outcome measure (accuracy of CMR versus SPECT).

<table>
<thead>
<tr>
<th>Measure</th>
<th>CMR (n=598)</th>
<th>SPECT (n=628)</th>
<th>p value (CMR vs SPECT)</th>
<th>CMR with CMR angio data excluded*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>86.3% (81.5-90.0)</td>
<td>66.5% (60.4-72.1)</td>
<td>p&lt;0.0001</td>
<td>81.6% (76.5-85.8)</td>
</tr>
<tr>
<td>Specificity</td>
<td>83.2% (79.1-86.6)</td>
<td>82.6% (78.5-86.1)</td>
<td>NS</td>
<td>85.9% (82.1-88.9)</td>
</tr>
<tr>
<td>PPV</td>
<td>77.0% (71.7-81.5)</td>
<td>71.4% (65.3-76.9)</td>
<td>NS</td>
<td>78.9% (73.7-83.3)</td>
</tr>
<tr>
<td>NPV</td>
<td>90.3% (86.7-93.0)</td>
<td>79.1% (74.8-82.8)</td>
<td>p&lt;0.0001</td>
<td>87.8% (84.2-90.6)</td>
</tr>
</tbody>
</table>

CMR = cardiovascular magnetic resonance; NPV = negative predictive value; NS = not significant; PPV = positive predictive value, SPECT = single-photon emission computed tomography; n, number of patients.

*In order to compare equivalent components of the CMR protocol to the SPECT protocol, an analysis of diagnostic performance was conducted where the CMR angiogram images were excluded from the analysis.

The data were also analysed excluding the results for CMR with angiography; 55 per cent of results were analysable. The outcomes varied slightly from those obtained when CMR with angiography was included, but the authors concluded that diagnostic accuracy did not differ significantly (Table 2).

Receiver operating curve analyses were conducted. Results showed that stress CMR significantly out-performed SPECT. Stress perfusion CMR was better than SPECT even when the angiographic cut-off value for a clinically significant stenosis was adjusted to ≥50 per cent for left main stem and ≥ 50 per cent for left anterior descending, left circumflex artery and right coronary artery. Stress perfusion CMR also performed better than SPECT when single vessel and multi-vessel disease groups were analysed separately (all p<0.0001).
The authors described their study as the ‘largest, prospective, real world assessment of CMR’ and noted that their study population represented a typical hospital outpatient population versus populations in some earlier studies where patients were highly selected, for example, the MR-IMPACT I study where disease prevalence was high. They concluded that CMR offers an accurate assessment of single-vessel and multi-vessel CHD, irrespective of the cut-off used for severity of clinically significant angiographic stenosis (≥ 50% or 70%).

Schwitter et al, MR-IMPACT II study

The Magnetic Resonance Imaging for Myocardial Perfusion Assessment in Coronary Artery Disease Trial (MR-IMPACT II) compared the diagnostic performance of perfusion-CMR and SPECT for the detection of CHD using X-ray coronary angiography as the reference standard. The study followed on from the phase II MR-IMPACT I trial.

Across 33 centres, a total of 533 patients who were scheduled for X-ray coronary angiography or SPECT examination (two- or three-head cameras, various vendors) for clinical reasons and met study inclusion criteria were enrolled. It was not stated whether patients were enrolled consecutively. For the angiography, CHD was defined as presence of ≥50 per cent artery diameter stenosis (i.e. ≥75 per cent area reduction) measured in two orthogonal planes, or history of previous MI without significant stenosis, in vessels of diameter ≥ 2 mm.

A total of 515 patients (mean age 60 years, 73% men, 95% Caucasian) received CMR (1.5 Tesla scanners, various vendors) within 4 weeks (before or after) of receiving X-ray coronary angiography and SPECT. CMR consisted of adenosine stress perfusion imaging, rest perfusion imaging and a late enhancement study. Stress and rest SPECT examinations used 99mTc- or 201TI-tracer, and either physical stress or adenosine dose, as for CMR. Most patients underwent X-ray coronary angiography as the last test. CMR data were analysed visually by three fully-blinded readers in an independent core laboratory, while SPECT data were analysed visually by three fully-blinded readers in a separate core laboratory.

The primary study endpoint was the non-inferiority of both sensitivity and specificity for CMR versus SPECT for the detection of CHD, assessed through a binary approach (i.e. single threshold applied to images). The primary outcome analysis included patients with complete data from all three modalities. Sensitivity, specificity, and negative and positive predictive values were calculated as secondary endpoints, as was the safety profile of CMR. The study was financially supported by GE Healthcare. Three of the authors reported acting as consultants for GE Healthcare and receiving honoraria, while one was a GE Healthcare employee responsible for the statistical analyses.

Safety

No deaths or severe drug-related adverse events occurred in the 515 patients who received CMR. Seventy-four patients (14%) experienced a total of 114 adverse events of mild to
moderate severity, which included angina pectoris, headache, chest pain and injection site bruising.

**Effectiveness**

For the primary outcome measure (binary sensitivity and specificity of CMR versus SPECT) the following results were obtained:

- Sensitivity 0.67 versus 0.59, \(p=0.024\)
- Specificity 0.61 versus 0.72, \(p=0.038\).

Table 3 displays results for the secondary outcome measure (accuracy of CMR versus SPECT).

**Table 3** Diagnostic accuracy: CMR versus SPECT

<table>
<thead>
<tr>
<th>Measure</th>
<th>CMR (Mean ± SD)</th>
<th>SPECT (Mean ± SD)</th>
<th>(p) value (CMR vs SPECT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>75% ± 7%</td>
<td>59% ± 10%</td>
<td>(p=0.03)</td>
</tr>
<tr>
<td>Specificity</td>
<td>59% ± 8%</td>
<td>72% ± 14%</td>
<td>(p=0.03)</td>
</tr>
<tr>
<td>PPV</td>
<td>70% ± 5%</td>
<td>73% ± 8%</td>
<td>NS</td>
</tr>
<tr>
<td>NPV</td>
<td>65% ± 5%</td>
<td>60% ± 3%</td>
<td>NS</td>
</tr>
<tr>
<td>Accuracy</td>
<td>68% ± 5%</td>
<td>65% ± 3%</td>
<td>NS</td>
</tr>
</tbody>
</table>

CMR = cardiovascular magnetic resonance, NPV = negative predictive value; NS = not significant; PPV = positive predictive value; SD = standard deviation; SPECT = single-photon emission computed tomography.

These results indicate that CMR is able to correctly identify patients with CHD but has greater difficulty identifying those patients without CHD.

Further secondary analyses, including receiver operating curve analysis and comparison of the diagnostic performance of CMR versus SPECT in specific subpopulations (e.g. multi-vessel disease, men, women, patients without prior MI), were presented by the authors in a separate paper.\(^8\)

The authors stated that the aim of their study was to assess test performances in a realistic clinical environment across a substantial number of countries, and not to repeat the results of a small number of leading high-performance centres. They concluded that the sensitivity of CMR to detect CHD was superior to SPECT, while its specificity was inferior to that of SPECT. The findings are not applicable to patients with decompensated heart failure, after bypass surgery, or with relevant arrhythmia.

**Economic evaluation**

The Toronto Health Economics and Technology Assessment collaborative conducted a systematic review of economic literature and a decision-analytic cost-effectiveness analysis to evaluate the relative cost-effectiveness of five non-invasive cardiac imaging technologies for diagnosing CHD, which included CMR and SPECT.\(^9\) The systematic literature review located one study that compared the incremental cost-effectiveness of CMR versus SPECT;
this study found that SPECT was dominant over CMR for producing lower costs and a greater number of quality-adjusted life years (QALYs). Based on estimates from the Ontario Health Insurance Plan and Ontario Case Costing Initiative databases, CMR was estimated to cost C$835.47 compared to C$634.63 for SPECT (A$803.86 vsA$610.66,via xe.com, 15 Jan 2013). The cost-effectiveness analysis showed that both CMR and SPECT were dominated (i.e. higher cost, worse outcome) by stress echocardiography in outpatients with stable chest pain, but only CMR was dominated by stress echocardiography in inpatients admitted with acute chest pain. No direct comparison of CMR and SPECT was reported by the authors.

A recent Japanese cost-effectiveness analysis specifically compared CMR and SPECT for diagnosis of CHD in outpatients with chest pain.10 Based on clinical effectiveness data from published studies and reimbursement data from Japanese healthcare insurance for the year 2007, the analysis found CMR reduced the diagnostic cost of CHD by ¥44,188 (A$467.35,via xe.com, 15 Jan 2013) per patient compared to SPECT (¥181,275 vs ¥225,463 [A$1,917.58vs A$2,385.11,via xe.com, 15 Jan 2013]), but increased the combined diagnostic and treatment cost of CHD by ¥17,943 (A$189.84, via xe.com, 15 Jan 2013) per patient (¥644,239 vs ¥626,296 [A$6,816.28 vs A$6,626.44; via xe.com, 15 Jan 2013]). The authors stated that per patient, CMR was cost-effective compared to SPECT for diagnosis alone, but was more expensive than SPECT in the comparison of the combined diagnostic and treatment costs of CHD. This was attributed primarily to the greater diagnostic ability of CMR and thus the higher number of treatment opportunities available. Overall, the cost-effectiveness ratios of the two technologies were similar.

**Ongoing research**

**EXACT (NCT01592565)11**

A study comparing CMR to SPECT for detecting CHD is described at clinicaltrials.gov. This study will take place at the Ohio State University, and is listed as currently recruiting patients. Trial arms include: (1) CMR in combination with exercise stress testing and (2) SPECT. Any patient referred for stress SPECT with known or suspected ischemic heart disease and the ability to perform adequate treadmill stress testing will be enrolled (estimated enrolment n=227). Exercise nuclear and CMR examinations will include aggregate assessment of exercise parameters, electrocardiogram findings, myocardial perfusion and segmental left ventricular wall motion (CMR only). Viability will be independently reviewed offline by a consensus of two reviewers blinded to the results of the other imaging study, and each test will be classified as negative/adequate stress, negative/inadequate stress, positive for ischemia, or fixed abnormality/no ischemia. Final data collection is estimated for August 2013.
CE-MARC2 (NCT01664858)\textsuperscript{12}

An RCT of non-invasive imaging for patients with stable angina is described at clinicaltrials.gov, although recruitment has not yet started (information last verified October 2012).\textsuperscript{12} The study will take place at the University of Leeds, as did CE-MARC.\textsuperscript{13} Trial arms include: (1) 3-T CMR-guided management, (2) SPECT-guided management and (3) NICE-guidelines-based management including the imaging strategy specified according to pre-test likelihood of CHD. Outpatients with suspected stable angina will be enrolled (estimated n=1200). The primary outcome is the rate of unnecessary invasive coronary angiography and secondary outcomes include major adverse cardiovascular events, imaging accuracy, quality of life and cost-effectiveness. Final data collection is estimated for September 2016 and study completion for September 2018.

Other issues

A number of comments were published following the release of the Greenwood et al study.\textsuperscript{5,14,15} The comments generally pointed out perceived shortcoming of Greenwood’s methods and defended the utility of SPECT, for example:

- Interpretation of SPECT results (including scoring) was not clearly described.
- SPECT technology might have been out-dated versus cutting-edge CMR.
- A large number of patients were excluded, possibly skewing the study population.

The authors replied to these criticisms, providing further detail and arguments as to why these concerns are not relevant.\textsuperscript{16} They also agreed with one writer that the reference standard, X-ray coronary angiography, is imperfect for determining the haemodynamic significance of coronary artery lesions; however, they justified the choice of this reference standard by stating that they had aimed to be pragmatic and reflect real world practice.

Similarly, one comment was published relating to the Schwitter et al study,\textsuperscript{6,17} highlighting perceived limitations regarding its value for deciding between imaging techniques. These limitations included:

- The definition of CHD used in the study was potentially inappropriate.
- Patients excluded from the study were not discussed, leading to questions about the generalisability of results.
- SPECT diagnosis may not have been performed in an optimal manner.

The study authors replied to these comments, stating that their study reflected real-world clinical practice and providing their rationale as to why the issues raised were not a concern.\textsuperscript{18} They did agree that it would be desirable for as much data as possible to be available on the performance of the two techniques, and that CMR examinations should only be performed by experienced experts.
Summary of findings

‘CE-MARC’, a large comparative, prospective trial performed in the UK, and ‘MR-IMPACT II’, a large multicentre, multivendor prospective trial conducted across Europe and the US, provided clinical evidence for this report. The study by Greenwood et al compared the diagnostic accuracy of CMR to the reference standard (X-ray coronary angiography) and to non-invasive imaging via SPECT. As compared with the findings at angiography, CMR showed high rates of sensitivity (86.5%) and NPV (90.5%) with lower values for specificity and PPV (83.4% and 77.2%, respectively). Performance compared with SPECT showed statistically significant superiority with respect to sensitivity and NPV (p<0.0001 for both), although specificity and PPV were not significantly different.

In the MR-IMPACT II study, reported rates of sensitivity, specificity, PPV and NPV for CMR and SPECT were all noticeably lower than those in the ‘CE-MARC’ study, likely due to the multicentre nature of the study. While CMR showed statistically significant superiority with respect to sensitivity, it showed statistically significant inferiority with respect to specificity. While limited in quantity, economic evidence generally found CMR to be less cost-effective compared to SPECT.

‘CE-MARC2’ will soon be underway at the same UK institution as the ‘CE-MARC’ trial and will consist of three treatment arms comparing 3-T CMR-guided management to SPECT-guided management and to NICE-guidelines-based management. The primary outcome will be the rate of unnecessary invasive coronary angiography; economic analysis and assessment of quality of life will be addressed as well.

HealthPACT assessment

Based on the statistically significant improvements in sensitivity offered by CMR (compared with SPECT) seen in the small evidence base available and the potential for further evidence becoming available in the future, for both CMR and CTCA, this technology will be monitored for a period of 24 months.

Number of studies included

All clinical evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of studies</td>
<td>2</td>
</tr>
<tr>
<td>Total number of Level II diagnostic accuracy studies</td>
<td>1</td>
</tr>
<tr>
<td>Total number of Level III-1 diagnostic accuracy studies</td>
<td>1</td>
</tr>
</tbody>
</table>
References


**Search criteria to be used (MeSH terms)**

MeSH: coronary disease, diagnosis, specificity and sensitivity, magnetic resonance angiography, tomography, emission-computed, single-photon

Keywords: coronary heart disease, diagnostic, specificity and sensitivity, cardiovascular magnetic resonance, single-photon emission computed tomography