Use of Cardiac Magnetic Resonance Angiography in Adults and Children

Draft Key Questions: Public Comment and Response

April 9, 2021
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Draft Key Questions: Public Comment and Response

Provided by:

Center for Evidence-based Policy
Oregon Health & Science University

April 9, 2021
Responses to Public Comment on Draft Key Questions

The Center for Evidence-based Policy is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

Draft key question document comments received:

- Chiara Bucciarelli-Ducci, Chief Executive Officer, and Karen Ordovas, Board of Trustees Secretary Treasurer, Society for Cardiovascular Magnetic Resonance (SCMR)

Specific responses pertaining to submitted comments are shown in Table 1.
Table 1. Responses to Comments on Draft Key Questions for Vagal Nerve Stimulation for Epilepsy and Depression

<table>
<thead>
<tr>
<th>Comments</th>
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<td><strong>General Comments:</strong></td>
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<td><strong>Supporting Evidence:</strong> Adults with suspected CAD</td>
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<td>There are several studies evaluating the diagnostic accuracy of CMRA compared to coronary CTA or invasive coronary angiography for the diagnosis of coronary artery disease. CMRA has very good accuracy for identification of obstructive coronary disease in a clinical research setting. A multicenter study has evaluated the diagnostic accuracy of CMRA in a “real life” environment and has shown that the test performs very well when compared to standard of care. The study included 127 patients with suspected CAD. The areas under the receiver-operator characteristic curve from coronary MRA images according to vessel- and patient-based analyses were 0.91 (95% confidence interval [CI]: 0.87 to 0.95) and 0.87 (95% CI: 0.81 to 0.93), respectively. The sensitivity, specificity, positive and negative predictive values, and accuracy of MRA according to a patient-based analysis were 88% (49 of 56, 95% CI: 75% to 94%), 72% (51 of 71, 95% CI: 60% to 82%), 71% (49 of 69, 95% CI: 59% to 81%), 88% (51 of 58, 95% CI: 76% to 95%), and 79% (100 of 127, 95% CI: 72% to 86%), respectively. The number of studies on coronary MR angiography cost-effectiveness is still limited. An increase in trained investigators and multicenter studies employing up-to-date MR angiographic techniques are essential to prove the value of coronary MR angiography for ruling out significant CAD.</td>
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<td>In summary, CMRA can be used as an alternative to CTA and invasive coronary angiography for identification of coronary artery disease, especially in patients with contraindication for iodinated contrast media due to allergy. However, it is not recommended as the first line test for assessment of obstructive coronary artery disease in adults. It must be noted that CMRA is a very useful test in combination with other cardiovascular MR examinations such as stress CMR and Cardiac MRI with and without contrast for anatomy and function, as it can help delineate the culprit coronary lesion causing ischemia or myocardial infarction.</td>
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<td>CMRA is the preferred technique for the diagnosis of coronary artery anomaly in adults and children, with a level I indication based on the American Heart Association and American College of Cardiology guideline for management of patients with congenital heart diseases such as coronary anomaly. CMRA has several advantages for diagnosing coronary artery anomalies. CMRA does not require ionizing radiation (likely to be an important consideration among adolescents and younger adults with suspected anomalous CAD) or iodinated contrast agents. Both contrast and non-contrast coronary MRA methods have been used with similar excellent result, including several instances in which the 3D aspects of coronary CMR were of marked utility relative to 2D projection techniques such as invasive coronary angiography. The volumetric nature of CMR makes it ideal in visualizing the proximal course that may not be apparent by two-dimensional projection X-ray angiography. CMRA easily identifies inter-arterial (traveling between the ascending aorta and pulmonary artery) vs. retroaortic coronary anomalies, with greater concern regarding sudden death risk in the former. Navigator-triggered noncontrast coronary CMRA further removes the requirement for exogenous iodinated contrast or Gadolinium agent to image the origin and proximal course of the coronary arteries.</td>
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<td><strong>Supporting Evidence:</strong> Adults who have undergone coronary artery bypass graft (CABG) surgery</td>
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<td>Supporting Evidence: Direct harms</td>
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<td>D. Adults and children with comorbidities – In the pediatric population, especially with co-morbidities in need of multiple and serial imaging studies, CMRA has advantages compared with iodinating radiation techniques such as CT and conventional coronary angiogram.</td>
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**Comments**

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A few studies have demonstrated the ability of a CMRA imaging approach to avoid additional imaging tests or invasive procedures in pediatric patients with CHD, and therefore avoiding expenses. A study evaluating the cost savings after Cardiovascular magnetic resonance imaging in 361 consecutive patients who underwent CMR over a period of 6 months showed that CMR results avoided invasive procedures in 38 (11%) patients and prevented additional diagnostic testing in 26 (7%) patients. Comparison of health care savings using CMR as opposed to current standards of care showed a net cost savings of $833,037, i.e., per patient cost savings of $2308.

**References**


- Use of Intravenous Gadolinium-based Contrast Media in Patients with Kidney Disease: Consensus Statements from the American College of Radiology and the National Kidney Foundation Jeffrey
Comment: Chiara Buccarelli-Ducci, Chief Executive Officer, and Karen Or dovas, Board of Trustees Secretary Treasurer, Society for Cardiovascular Magnetic Resonance (SCMR)

- **Risk of Nephrogenic Systemic Fibrosis in Patients With Stage 4 or 5 Chronic Kidney Disease Receiving a Group II Gadolinium-Based Contrast Agent: A Systematic Review and Meta-analysis.** Sean A. Woolen, MD, MS1,2; Prasad R. Shankar, MD1,2; Joel J. Gagnier, ND, MSc, PhD3,4; et al. JAMA Intern Med. 2020;180(2):223-230. doi:10.1001/jamainternmed.2019.5284


Abbreviation. 2D: 2-dimensional; 3D: 3-dimensional; ACC: American College of Cardiology; AHA: American Heart Association; CABG: coronary artery bypass graft; CAD: coronary artery disease; CCTA: coronary computed tomography angiogram; CHD: congenital heart disease; CI: confidence interval; CKD: chronic kidney disease; CMR: cardiac magnetic resonance; CMRA: cardiac magnetic resonance angiography; CT: computed tomography; CTA: computed tomography angiogram; eGFR: estimated glomerular filtration rate.
glomerular filtration rate; GBCA: gadolinium based contrast agents; GBCM: gadolinium based contrast media; JAMA: Journal of the American Medical Association; MR: magnetic resonance; MRA: magnetic resonance angiography; MRI: magnetic resonance imaging; NSF: nephrogenic systemic fibrosis; NSK: nephrogenic systemic fibrosis [assumed]; SCMR: Society for Cardiovascular Magnetic Resonance; SSFP: steady-state free procession.
To: Washington State Healthcare Authority

From: Society for Cardiovascular Magnetic Resonance

Date: 3/30/21

RE: Request for Comments – CMRA in Adults and Children

This is a document from the Society for Cardiovascular Magnetic Resonance (SCMR) in response to the Washington State Healthcare Authority (WSHA) request for public comments for clinical utility, diagnostic validity, cost-effectiveness and potential harm associated with the use of Cardiovascular Magnetic Resonance Angiography in Adults and Children. The request has particular interest in data relative to adults with suspected CAD (e.g., symptomatic patients), adults with suspected coronary vessel anomalies, adults who have undergone CABG surgery, adults being assessed for cardiac device lead placement, and children with suspected or confirmed congenital heart disease, particularly older children with repaired congenital heart disease.

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The SCMR is the largest international scientific society for the use of cardiovascular magnetic resonance, and the Executive Board of Directors has prepared this document in collaboration with the SCMR advocacy committee. Response to specific WSHA questions are outlined below.
Key Questions

1. What is the evidence for the diagnostic validity (i.e., accuracy) and clinical utility (i.e., effectiveness) of CMRA (with or without contrast) in adults with suspected or confirmed CAD and children with suspected or confirmed congenital heart disease? The use of CMRA will be assessed in the following populations:

   A. Adults with suspected CAD (e.g., symptomatic patients)

   There are several studies evaluating the diagnostic accuracy of CMRA compared to coronary CTA or invasive coronary angiography for the diagnosis of coronary artery disease. CMRA has very good accuracy for identification of obstructive coronary disease in a clinical research setting. A multicenter study has evaluated the diagnostic accuracy of CMRA in a “real life” environment and has shown that the test performs very well when compared to standard of care. The study included 127 patients with suspected CAD. The areas under the receiver-operator characteristic curve from coronary MRA images according to vessel- and patient-based analyses were 0.91 (95% confidence interval [CI]: 0.87 to 0.95) and 0.87 (95% CI: 0.81 to 0.93), respectively. The sensitivity, specificity, positive and negative predictive values, and accuracy of MRA according to a patient-based analysis were 88% (49 of 56, 95% CI: 75% to 94%), 72% (51 of 71, 95% CI: 60% to 82%), 71% (49 of 69, 95% CI: 59% to 81%), 88% (51 of 58, 95% CI: 76% to 95%), and 79% (100 of 127, 95% CI: 72% to 86%), respectively.

   The number of studies on coronary MR angiography cost-effectiveness is still limited. An increase in trained investigators and multicenter studies employing up-to-date MR angiographic techniques are essential to prove the value of coronary MR angiography for ruling out significant CAD.

   In summary, CMRA can be used as an alternative to CTA and invasive coronary angiography for identification of coronary artery disease, especially in patients with contraindication for iodinated contrast media due to allergy. However, it is not recommended as the first line test for assessment of obstructive coronary artery disease in adults. It must be noted that CMRA is a very useful test in combination with other cardiovascular MR examinations such as stress CMR and Cardiac MRI with and without contrast for anatomy and function, as it can help delineate the culprit coronary lesion causing ischemia or myocardial infarction.

   B. Adults with suspected coronary vessel anomalies

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adolescents and younger adults with suspected anomalous CAD) or iodinated contrast agents. Both contrast and non-contrast coronary MRA methods have been used with similar excellent result, including several instances in which the 3D aspects of coronary CMR were of marked utility relative to 2D projection techniques such as invasive coronary angiography.

The volumetric nature of CMR makes it ideal in visualizing the proximal course that may not be apparent by two-dimensional projection X-ray angiography. CMRA easily identifies inter-arterial (traveling between the ascending aorta and pulmonary artery) vs. retroaortic coronary anomalies, with greater concern regarding sudden death risk in the former. Navigator-triggered noncontrast coronary CMRA further removes the requirement for exogenous iodinated contrast or Gadolinium agent to image the origin and proximal course of the coronary arteries.

C. Adults who have undergone coronary artery bypass graft (CABG) surgery

There is limited data on the accuracy of coronary MRA for assessment of CABG patency. The largest study in the topic included 86 grafts and showed sensitivity, specificity, and positive and negative predictive values for stenosis in arterial grafts of 95.2%, 96.8%, 80% and 99.4%, respectively, and in venous of 100%, 97.8%, 87.5% and 100%, respectively. CMRA is not recommended as a primary imaging modality for assessment of coronary bypass grafts, but can be used in patients with allergy to iodinated contrast or specific concerns regarding ionizing radiation.

D. Adults being assessed for cardiac device lead placement

A few studies have interrogated the accuracy of CMRA for delineation of coronary venous anatomy in preparation for cardiac device lead placement. The largest study included 31 patients who have undergone contrast enhanced high resolution coronary CMR angiography. That study showed the feasibility of using CMRA for delineation of coronary venous anatomy in all patients studied.

Three-dimensional MR coronary vein angiograms can be overlaid onto real-time time acquired x-ray images, to improve guidance for catheter implantation.

E. Children with suspected or confirmed congenital heart disease

Cardiovascular MR Angiography is a unique method for assessment of pediatric patients with congenital heart disease. Cardiovascular MRA has level I indication for imaging evaluation of multiple congenital heart diseases in the AHA/ ACC guidelines and ECVI guidelines. The method is particularly crucial for assessment of the thoracic aorta, pulmonary arteries, pulmonary veins and baffles/conduits, both before and after the repair of multiple CHD such as coarctation of the aorta, tetralogy of Fallot, partial anomalous pulmonary venous connection and transposition of great arteries.
Cardiovascular MRA techniques with and without contrast (time-of-flight, phase contrast, SSFP, and contrast-enhanced magnetic resonance angiography) provide the ability to visualize the moving blood and to generate images of vessel lumens that allow selective display of vascular anatomy in 3D projections. With improvements in scanner speed, it is now possible to perform rapid frame rate MRA, also known as time-resolved MR angiography, allowing direct visualization of flow dynamics, which may be important for assessment of vascular shunts or dissections.

2. What direct harms are associated with CMRA in adults with suspected or confirmed CAD and children with suspected or confirmed congenital heart disease? The harms of CMRA will be assessed in the following populations:

   A. Adults with suspected CAD (e.g., symptomatic patients)
   B. Adults with suspected coronary vessel anomalies
   C. Adults who have undergone CABG surgery
   D. Adults being assessed for cardiac device lead placement
   E. Children with suspected or confirmed congenital heart disease

Current American College of Radiology and National kidney foundation consensus statement defines that that there is minimal risk of renal dysfunction associated with the use of gadolinium agent from group II or III, currently in clinical use. The risk of nephrogenic systemic fibrosis (NSF) from group II GBCM in patients with advanced kidney disease is thought to be very low (zero events following 4931 administrations to patients with estimated glomerular filtration rate [eGFR] <30 mL/min per 1.73 m²; upper bounds of the 95% confidence intervals: 0.07% overall, 0.2% for stage 5D chronic kidney disease [CKD], 0.5% for stage 5 CKD and no dialysis).

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The less than minimal risks discussed here apply equally to the specific populations addressed in this document.

3. Do important diagnostic validity (i.e., accuracy) outcomes, clinical utility (i.e., effectiveness) outcomes, or direct harms of CMRA in adults with suspected or confirmed
CAD and children with suspected or confirmed congenital heart disease vary by the following populations or circumstances?

A. Sex (i.e., men, women) – In female pregnant patients and those in need of serial imaging, CMRA has advantages compared with iodinating radiation techniques such as CT and conventional coronary angiogram.

B. Adults with atypical symptoms of CAD – No specific variability in the utility or harm related to CMRA in this population has been reported.

C. Age, specifically in older adults - No specific variability in the utility or harm related to CMRA in this population has been reported.

D. Adults and children with comorbidities – In the pediatric population, especially with co-morbidities in need of multiple and serial imaging studies, CMRA has advantages compared with iodinating radiation techniques such as CT and conventional coronary angiogram.

E. Setting (e.g., high volume setting vs. low volume setting) - No specific variability in the utility or harm related to CMRA in this population has been reported.

4. What are the cost-effectiveness and other economic outcomes of CMRA in adults with suspected or confirmed CAD and children with suspected or confirmed congenital heart disease? The economic outcomes of CMRA will be assessed in the following populations:

A. Adults with suspected CAD (e.g., symptomatic patients)

There is little data on cost-effectiveness of coronary MRA compared to coronary CTA or catheter angiography for assessment of patients with suspected CAD, therefore most appropriateness criteria guidelines recommend this test for patients with allergy to iodinated contrast or those with specific concerns regarding radiation exposure with other methods.

B. Adults with suspected coronary vessel anomalies

There is no specific publication addressing the cost-effectiveness of an imaging approach using CMRA compared to CCTA or invasive coronary angiogram for the diagnosis of patients with anomalous coronary arteries.

C. Adults who have undergone CABG surgery

There is no specific publication addressing the cost-effectiveness of an imaging approach using CMRA compared to CCTA or invasive coronary angiogram for the assessment of CABG patency or other CABG complications.
D. Adults being assessed for cardiac device lead placement

There is no specific publication addressing the cost-effectiveness of an imaging approach using CMRA compared to CCTA or invasive coronary angiogram for the assessment of coronary venous anatomy prior to device lead placement.

E. Children with suspected or confirmed congenital heart disease

A few studies have demonstrated the ability of a CMRA imaging approach to avoid additional imaging tests or invasive procedures in pediatric patients with CHD, and therefore avoiding expenses. A study evaluating the cost savings after Cardiovascular magnetic resonance imaging in 361 consecutive patients who underwent CMR over a period of 6 months showed that CMR results avoided invasive procedures in 38 (11%) pts and prevented additional diagnostic testing in 26 (7%) pts. Comparison of health care savings using CMR as opposed to current standards of care showed a net cost savings of $833 037, ie, per patient cost savings of $2308.

Thank you for your consideration of these comments. If you have questions or require additional information, please contact Karen Ordovas, MD, MAS, SCMR Board Member and Chief, Cardiothoracic Imaging Section, Professor of Radiology, University of Washington, at ordovask@uw.edu.

Sincerely,

Chiara Buccarelli-Ducci, MD, PhD, FSCMR
Chief Executive Officer
SCMR

Karen Ordovas, MD, MAS, FSCMR
SCMR Board of Trustees Secretary Treasurer
References


2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines


Use of Intravenous Gadolinium-based Contrast Media in Patients with Kidney Disease: Consensus Statements from the American College of Radiology and the National Kidney Foundation Jeffrey C. Weinreb, MD • Roger A. Rodby, MD • Jerry Yee, MD • Carolyn L. Wang, MD • Derek Fine, MD • Robert J. McDonald, MD, PhD • Mark A. Perazella, MD • Jonathan R. Dillman, MD, MS • Matthew S. Davenport, MD From the American College of Radiology,
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Sean A. Woolen, MD, MS1,2; Prasad R. Shankar, MD1,2; Joel J. Gagnier, ND, MSc, PhD3,4; et al. JAMA Intern Med. 2020;180(2):223-230. doi:10.1001/jamainternmed.2019.5284


Cardiovascular Magnetic Resonance Imaging—Incremental Value in a Series of 361 Patients Demonstrating Cost Savings and Clinical Benefits: An Outcome-Based Study Vinayak A Hegde1,2, Robert WW Biederman3,4 and J Ronald Mikolich1,5

Clinical Medicine Insights: Cardiology Volume 11: 1–10