Washington State Health Care Authority

November 5, 2021 Meeting Materials
Health Technology Clinical Committee

Noninvasive cardiac imaging for coronary artery disease

Contents

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CURRICULUM VITAE **February, 2021**

JAMES N. KIRKPATRICK, MD
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1. PERSONAL DATA

Citizenship: USA
Place of Birth: Seattle, WA

2. EDUCATION

1989-1993	Bachelor of Arts in Politics, cum laude, Pomona College, Claremont, CA
1994 -1998	M.D. in Internal Medicine, Loma Linda University School of Medicine, Loma Linda, CA

3. POSTGRADUATE TRAINING

1998-1999	Intern, Categorical Internal Medicine, Yale New Haven Hospital
1999-2001	Resident, Categorical Internal Medicine, Yale New Haven Hospital
2001-2002	Fellow, Clinical Medical Ethics, MacLean Center for Clinical Medical Ethics, University of Chicago
2001-2002	Human Subject Protection/Biostatistics and Quantitative Methods, National Institutes of Health (Fulfills NIH criteria for principal investigator training in human subject protection), University of Chicago
2002-2003	Research Fellow, Echocardiography, University of Chicago
2003-2006	Fellow, Cardiovascular Disease, University of Chicago
2004-2005	Chief Cardiology Fellow, University of Chicago
2006	Level III Echocardiography Training, University of Chicago

4. FACULTY POSITIONS HELD

2006-2014	Assistant Professor, Department of Medicine, Cardiovascular Division at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine, Philadelphia, PA
2014-2015	Associate Professor, Department of Medicine, Cardiovascular Division at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine, Philadelphia, PA
2013-2014	Assistant Professor, Department of Medical Ethics and Health Policy, University of Pennsylvania School of Medicine (Secondary), Philadelphia, PA
2014-2015	Associate Professor, Department of Medical Ethics and Health Policy, University of Pennsylvania School of Medicine (Secondary), Philadelphia, PA
2015-present	Associate Professor, Department of Medicine, Division of Cardiology, University of Washington School of Medicine, Seattle, WA
2018-present	Section Chief, Cardiac Imaging, University of Washington Department of Medicine, Division of Cardiology, Seattle, WA
2019-present	Professor, Department of Medicine, Division of Cardiology, University of Washington School of Medicine, Seattle, WA
2019-present	Adjunct Professor, Department of Bioethics and Humanities, University of Washington School of Medicine, Seattle, WA

5. HOSPITAL POSITIONS HELD

2001-2006	Staff Internist, Lawndale Christian Health Center, Chicago, IL

2013-2015	Interim Associate Director of the Echocardiography Laboratory and Program, Hospital of the University of Pennsylvania, Philadelphia, PA
2013-2015	Physician co-Chair, Ethics Committee, Hospital of the University of Pennsylvania, University of Pennsylvania, Philadelphia, PA
2015-present	Director of Echocardiography, University of Washington Medical Center
2015-present	Ethics Consultant, Ethics Consultation Service, University of Washington Medical Center, Seattle, WA
2016-present	Chair, Ethics Committee, University of Washington Medical Center, Seattle, WA
2020-2021	D1 Governance Committee, Division of Cardiology

6. CURRENT EMPLOYMENT FOR WWAMI FACULTY- NONE

7. HONORS

1993	John Veig Memorial Prize for Academic Distinction (Government), Pomona College
1993	Graduate Cum Laude, Pomona College
1993	Distinction in Final Project, Pomona College
1995	Appleton and Lange Academic Medical Student Aware, Loma Linda University School of Medicine
1996	Honors in Psychiatry, Loma Linda University School of Medicine
1996	Honors in Pathophysiology, Loma Linda University School of Medicine
1997	Honors in Internal Medicine, Loma Linda University School of Medicine
1998	President's Award, Class of 1998, Loma Linda University School of Medicine
1998	Alpha Omega Alpha Medical Honor Society, Loma Linda University School of Medicine
1998	Harold J. Hoxie Award, Department of Medicine, Loma Linda University School of Medicine
2002	American Heart Association Fellows Travel Award for Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke
2009	Faculty Teaching Award, Cardiovascular Division, Department of Medicine, University of Pennsylvania
2010	Paper selected as one of the must-read papers in non-invasive cardiac imaging by editorial team at ThePreparedMinds.com for April, 2010.
2013	Certificate of Reviewing Excellence presented by Elsevier for Journal of the American Society of Echocardiography peer reviews.
2016-2019	American Society of Echocardiography Board of Directors
2017	Grace Marie Kaylor Endowed Award in Cardiology, Division of Cardiology, University of Washington
2017	Names to list of Top 27 Cardiologists Honor Roll—Forbes Magazine-Grand Rounds
2020-2023	Chair, American College of Cardiology Geriatrics Section
2021-2022	Chair Elect, American College of Cardiology Ethics Board
2020-2022	American Society of Echocardiography Foundation Board of Directors
2019	Vietnam Heart Institute Appreciation Award

8. BOARD CERTIFICATION

2006, 2019	National Board of Echocardiography--adult comprehensive echocardiography, level III certification
2006, 2016	American Board of Internal Medicine (Cardiovascular Diseases)

2011 American Board of Internal Medicine (Internal Medicine)

9. LICENSURE

2001-2008 State of Illinois Medical License #: 036104485
2006-present State of Pennsylvania Medical License #: MD429897
2015-present State of Washington Medical License #: MD60589898

10. DIVERSITY, EQUITY AND INCLUSION

EDI Committee—University of Washington Division of Cardiology

11. PROFESSIONAL ORGANIZATIONS

1998-2006 Member, American Medical Association
2001-present Member, American Society of Bioethics and Humanities
2002-present Member, American Society of Echocardiography
2008-present Fellow, American Society of Echocardiography
2003-present Member, American College of Cardiology
2010-present Fellow, American College of Cardiology
2003-2016 Member, American Heart Association
2011-2018 Member, Heart Failure Society of America

12. TEACHING RESPONSIBILITIES

Spring 2002 Course Director. Oak Forest Hospital and MacLean Center for Clinical Medical Ethics at the University of Chicago Conference on Spirituality and Healthcare, Oak Forest Hospital, Chicago, IL, 2002.

Mar, 2012 Course Director for Ethics of the Heart II: Ethical and Policy Challenges in Pediatric and Adult Congenital Heart Disease. The Penn Cardiovascular Institute and the Center for Bioethics. Friday - Saturday March 16-17, 2012 Perelman School of Medicine at the University of Pennsylvania and the Cardiac Center at Children's, Hospital of Philadelphia. Philadelphia, PA

Oct, 2010 Course Director, Ethics of the Heart I: Ethics and Policy Challenges in the Treatment of Advanced Heart Failure. October 8-9, 2010, Class of 1949 Auditorium, Houston Hall University of Pennsylvania Philadelphia, PA

A. Fellows and Post-Doctoral Fellows in Laboratory

2006-2009 Research Mentor, University of Pennsylvania Bioethics Masters Students (Todd Mendelson, Christina Papini, David Wolfe)

2007-2015 Echocardiography Research Mentor, Cardiovascular Division of Medicine/University of Pennsylvania School of Medicine: Fellows (Steven Farmer, Bonnie Ky, Jeffrey Testani, Elad Anter, Abby Khan, Amresh Raina, Hansie Mathelier, Vinay Kini, Dawn Pedtrotty), Residents (Jeffrey Ogbara, Anjali Fields, Vinay Kini, Harish Seetha Rammohan), Medical students (Amit Khera, Sachin Logani, Jennifer Chen)

2008-2015 Cardioethics Research Mentor, Cardiovascular Division of Medicine/University of Pennsylvania School of Medicine: Fellows (Steven Farmer, Abby Khan, Anjali Fields), Residents (Sarah Hull, Sachin Logani, Anjali Fields, Esther Pak), Public Health School Student (Karthik Kota)

2009 Faculty Liaison, Narrative Professionalism workshops for Cardiovascular Fellowship program

2015-present	Faculty Research Mentor, internal medicine resident, University of Washington (Pranothi Hiremath, Chinoso Opara)
2015-present	Faculty Research Mentor, cardiology fellows, University of Washington (Selma Carlson, Kathleen Kearney, Shalin Patel, Tiffany Chen, James Lee, Hans Huang, Amy Cheney, Jill Steiner, Vidang Nguyen, Andrew Harris, Minnu Mudigonda, Michael Morcos)
2017-present	Faculty Research Mentor, palliative care T32 fellows, University of Washington (Jill Steiner, Gwen Bernacki)
2020-present	Faculty Review Paper Mentor, cardiology fellows, University of Washington (Fitz Medhane and Tomio Tran)

B. Medical Students

2006-2015	Preceptor, Cardiology Module, Curriculum 2000 (MOD200C) University of Pennsylvania School of Medicine
2007-2015	Small Group Preceptor, MD301-600: Doctor-Patient Relationship: Culture and Communication, University of Pennsylvania School of Medicine
2008-2015	Small Group Preceptor, FR601: Bioethics and Professionalism and Respect for Persons, University of Pennsylvania School of Medicine
2008-2015	Small Group Preceptor, MD610: Ethics of Human Subjects Research, University of Pennsylvania School of Medicine
2009-2010	Faculty Mentor, 4th year University of Pennsylvania medical student research project. (Alexander Ende)
2012	Research Mentor, National Heart Lung and Blood Institute Summer Medical Student Short Term Research Program. (Penn Med first year student Arjeme Cave Committee, University of Washington Medical Cente

13. RESEARCH FUNDING

Current:

8/18-6/21	Sponsor: NIH R34 HL143279 Title: "Role of Statins in Slowing Rheumatic Heart Disease (RHD) Progression: A Feasibility Study for a Randomized Controlled Trial" Total Costs: $546,527 PI: Nona Sododhenia Role: Co-Investigator
4/20-3/21	NHLBI: 2T32HL125195-06 "Palliative Care Research Training Grant" Total Costs: $392,985 PI: J. Randall Curtis Role: Mentor
5/20-4/21	Sponsor: University of Nairobi UON-1R21TW011460-01 Title: "Subclinical cardiac dysfunction after hypertensive disorders in pregnancy" Total Costs: $119,428 PI: Carey Farquhar Role: Co-Investigator

7/20-4/25 Sponsor: NIDDK 1 R01 DK 121800-01A1
"Kidney Injury in Patients with Acute Decompensated Heart Failure"
Total Costs: $564,633
PI: Nisha Bansal
Role: Co-Investigator

9/20-5/21 Sponsor NIH 1D43TW011596-01
"Building Capacity"
Total Costs: $239,421
PI: Annette Fitzpatrick
Role: Mentor

Past:

7/2002-7/2003 Sponsor: American Society of Echocardiography Foundation
Title: Use of Hand Carried Ultrasound to Screen for Clinically Important Cardiac Disease in an Underserved Population
Total Costs: $25,000/annual direct costs, 50% effort
PI: Kirk T. Spencer, MD, PI
Role: Research Fellow

1/2011-12/2012 Sponsor: Greenwall Foundation
Title: Caregiver And Left Ventricular Assist Devices As Destination Therapy For End Stage Heart Failure: A Pilot Study Of A Journey
Total Costs: $52,223/annual direct costs, 7% effort
Role: PI

7/2011-5/2012 Sponsor: Mount Sinai Medical Center
Title: Promoting Independence Through Pain And Symptom Management, 0254-7892-4609
Total Costs: $0/annual direct costs
Role: PI

8/2011-7/2015 Sponsor: National Heart, Lung, And Blood Institute/NIH/DHHS
Title: Implementation of Cardiopulmonary Resuscitation Training For At-Risk Families
Total Costs: $346,363/annual direct costs. Advisory members do not receive effort as part of the committee
PI: Benjamin S. Abella
Role: Advisory Member

3/2012-2/2013 Sponsor: National Heart, Lung, And Blood Institute/NIH/DHHS
Title: Ethics And Policy Challenges In Pediatric And Adult Congenital Heart Disease, 1-R13-HL-112570-01
Total Costs: $15,000/annual direct costs
Role: PI

4/2013-8/2015 Sponsor: NHLBI
Title: Cardiac Surgical Techniques to treat ventricular and aortic remodeling, RFA-A-HL-13-017, 5UM1HL088957

Total Costs: $11,842/annual direct costs, .6% effort, effort is 0.6 calendar months
PI: Michael Acker
Role: Site Co-PI

10/01/14-09/30/18
Sponsor: NASA. NNX14AN49G
Title: Biomarkers as Predictors of Resiliency and Susceptibility to Stress in Space Flight.
Total Costs: $325,646
PI: Namni Goel
Role: Co-Investigator

7/2016-6/2019
Sponsor: Locke Charitable Research Grant, University of Washington.
Title: "Patient & Partner Intimacy in Patients with LVADs."
Total Costs: $25,000
Role: PI

3/2019-3/2020
Sponsor: American College of Cardiology
Title: "Eliciting TAVR Perioperative Code Status"
Total Coasts: $10,000
Role: Co-PI

14. BIBLIOGRAPHY

1. Publications in Refereed Journals

1. Sugeng L, **Kirkpatrick JN**, Lang RM, Bednarz JE, Decara JM, Lammertin G, Spencer KT. Biplane stress echocardiography using a prototype matrix-array transducer. *J Am Soc Echocardiogr*. 2003 Sep;16(9):937-941. PMID: 12931105
2. **Kirkpatrick JN**, Ring M, Lang, RM. Expanding the differential diagnosis of hemoptysis: mycotic aortic aneurysms. *Rev Cardiovasc Med*. 2003 Summer;4(3):180-183. PMID: 12949444
3. Spencer KT, Lang RM, **Kirkpatrick JN**, Mor-Avi V. Assessment of global and regional left ventricular diastolic function in hypertensive heart disease using automated border detection techniques. *J Am Soc Echocardiogr*. 2003 Oct; 20(7):673-681. PMID: 14536017
4. Spencer KT, Mor-Avi V, **Kirkpatrick JN**, Gorcsan J, Kimball TR, Monaghan MJ, Perez JE, Weinert L, Bednarz J, Edelman K, Glascock B, Hancock J, Baumann C, Lang RM. Normal values of left ventricular systolic and diastolic function derived from signal-averaged acoustic quantification waveforms: a multicenter study. *J Am Soc Echocardiogr*. 2003 Dec;16(12): 1244-1251. PMID: 14652603
5. ***Kirkpatrick JN**, Wong T, Bednarz JE, Spencer KT, Sugeng L, Ward RP, DeCara JM, Weinert L, Krausz T, Lang RM. Differential diagnosis of cardiac masses using contrast echocardiographic perfusion imaging. *J Am Coll Cardiol*. 2004 Apr 21;43(8):1412-1419. PMID: 15093876
6. Spencer KT, **Kirkpatrick JN**, Mor-Avi V, Decara JM, Lang RM. Age Dependency Myocardial of the Tei Index of Myocardial Performance. *J Am Soc Echocardiogr*. 2004 Apr;17(4):350-352. PMID: 15044869
7. **Kirkpatrick JN**, Davis A, DeCara JM, Hong AE, Kurtz PL, Balasia B, Spencer KT. Hand-carried cardiac ultrasound as a tool to screen for important cardiovascular disease in an underserved minority health care clinic. *J Am Soc of Echocardiogr*. 2004May;17(5):399-403. PMID: 15122177

8. Kaldjian LC, Wu BJ, **Kirkpatrick JN**, Thomas-Geevarghese A, Vaughan-Sarrazin M. Medical house officers' attitudes toward vigorous analgesia, terminal sedation, and physician-assisted suicide. *Am J Hosp Palliat Care.* 2004 Sep-Oct;21(5):381-387. PMID: 15510576
9. **Kirkpatrick JN**, Mahowald MB. Golden rule reasoning in clinical medicine: Theoretical and empirical aspects. *J Clin Ethics*. 2004 Fall;15(3):250-260. PMID: 15630868
10. Everett ME, **Kirkpatrick JN**, Lang RM. Noncompaction of the myocardium complicated by coronary artery embolism. *J Am Soc Echocardiogr*. 2005 Feb;18(2):194-196. PMID: 15682061
11. DeCara JM, **Kirkpatrick JN**, Spencer KT, Ward RP, Kasza K, Furlong K, Lang RM. Use of hand-carried ultrasound devices to augment the accuracy of medical student bedside cardiac diagnoses. *J Am Soc Echocardiogr*. 2005 Mar;18(3):257-263. PMID: 15746716
12. **Kirkpatrick JN**, Nash K, Duffy TP. Well rounded. *Arch Intern Med*. 2005 May 28;165(6):613-616. PMID: 15795335
13. **Kirkpatrick JN**, Belka V, Furlong K, Balasia B, Jacobs LD, Corcoran M, Anderson AS, Pastoret A, Spencer KT. Effectiveness of echocardiographic imaging by nurses to identify left ventricular systolic dysfunction in high-risk patients. *Am J* Cardiol. 2005 May 15;95(10): 1271-1272. PMID: 15878012
14. **Kirkpatrick JN**, Lang RM, Fedson SE, Anderson AS, Bednarz J, Spencer KT. Automated border detection on contrast enhanced echocardiographic images. *Int J Cardiol*. 2005 Aug;103(2):164-167. PMID: 16080975
15. Ward RP, Leeper NJ, **Kirkpatrick JN**, Lang RM, Sorrentino MJ, Williams KA. The effect of preoperative statin therapy on cardiovascular outcomes in patients undergoing infrainguinal vascular surgery. *Int J* Cardiol. 2005 Oct 10;104(3):264-268. PMID: 16186054
16. Ghani SN, **Kirkpatrick JN**, Spencer KT, Smith GL, Burke MC, Kim SS, Desai AD, Knight BP. Rapid assessment of left ventricular systolic function in a pacemaker clinic using a hand-carried ultrasound device. *J Interv Card Electrophysiol*. 2006 Jun;16(1):39-43. PMID: 17051437
17. Brennan JM, Ronan A, Goonewardena S, Blair JEA, Hammes M, Shah D, Vasaiwala S, **Kirkpatrick JN**, Spencer KT. Hand-carried ultrasound measurement of the inferior vena cava for assessment of intravascular volume status in the outpatient hemodialysis clinic. *Clin J Am Soc* Nephrol. 2006 Jul;1(4):749-753. PMID: 17699282
18. **Kirkpatrick JN,** Burke MC, Knight BP. Postmortem analysis and retrieval of implantable pacemakers and defibrillators. *N Engl J* Med. 2006 Apr 13;354(15):1649-1650. PMID: 16611964.
19. **Kirkpatrick JN**, Ghani SN, Burke MC, Knight BP. Postmortem interrogation and retrieval of implantable pacemakers and defibrillators: A Survey of Morticians and Patients. *J Cardiovasc Electrophysiol*. 2007 May;18(5):478-482. PMID: 17313530
20. Brennan JM, Blair JE, Goonewardena S, Ronan A, Shah D, Vasaiwala S, Brooks E, Levy A, **Kirkpatrick JN**, Spencer KT. A Comparison by Medicine Residents of Physical Examination versus Hand-carried Ultrasound for Estimation of Right Atrial Pressure. *Am J* Cardiol. 2007 Jun;99(11):1614-6. PMID: 17531592
21. BrennanJM, Blair JE, Goonewardena S, Ronan A, Shah D, Vasaiwala S, **Kirkpatrick JN**, Spencer KT. Reappraisal of the use of inferior vena cava for estimating right atrial pressure. *J Am Soc Echocardiogr*. 2007 Jul;20(7):857-861. PMID: 17617312
22. **Kirkpatrick JN**, Vannan MA, Narula J, Lang RM. Echocardiography in heart failure - Applications, utility, and new horizons. *J Am Col Cardiol*. 2007 Jul 31;50(5): 381-396. PMID: 17662389
23. **Kirkpatrick JN**, Guger CJ, Arnsdorf MF, Fedson SE. Advance directives in the cardiac care unit. *Am Heart J*. 2007 Sep;154(3): 477-481. PMID: 17719293

24. Glassberg H, **Kirkpatrick JN**, Ferrari VA: Imaging studies in patients with heart failure: current and evolving technologies. *Crit Care Med*. 2008 Jan;36(1 Suppl):S28-39. Doi: 10.1097/01.ccm.0000297163.25900.63. PMID: 18158474
25. Rahmouni HW, Ky, B, Plappert T, Duffy K, Wiegers SE, Ferrari VA, Keane MG, **Kirkpatrick JN**, Silvestry FE, St John Sutton M. Clinical Utility of Automated Assessment of Left Ventricular Ejection Fraction using Artificial Intelligence-assisted Border Detection. *Am Heart J*. 2008 Mar;155(3):562-570. Doi: 10.1016/j.ahj.2007.11.002. PMID: 18294497
26. **Kirkpatrick JN**, Ghani SN, Spencer KT. Hand carried echocardiography screening for LV systolic dysfunction in a pulmonary function laboratory. *Eur J* Echocardiogr. 2008 May;9(3): 381-3. PMID: 17697799
27. **Kirkpatrick JN**, Keane MG. Future Potential of Echocardiography in Heart Failure. *Future Cardiol*. 2008 May;4(3):299-319. Doi: 10.2217/14796678.4.3.299. PMID: 19804334
28. **Kirkpatrick JN**, Knight BP. The management of implantable cardiac devices at the end of life. *Progress in Palliative Care* 16(5-6): 250-256, 2008.
29. **Kirkpatrick JN**, Ky B, Rahmouni HW, Chirinos JA, Farmer SA, Fields AV, Ogbara J, Eberman KM, Ferrari VA, Silvestry FE, Keane MG, Opotowsky AR, St John Sutton M, Wiegers SE. Application of Appropriateness Criteria in Outpatient Transthoracic Echocardiography. *J Am Soc Echocardiogr*. 2009 Jan; 22(1):53-59. Doi: 10.1016/j.echo.2008.10.020. PMID: 19131002. Presented at the American Society of Echocardiography Scientific Sessions, 2008.
30. Mark DG, Hayden GE, Ky B, Paszczuk A, Pugh M, Matthews S, Horan A, Gracias VH, **Kirkpatrick JN**, Dean AJ: Hand-carried echocardiography for assessment of left ventricular filling and ejection fraction in the surgical intensive care unit. *J Critl Care*. 2009 Sep;24(3):470e1-7. Doi: 10.1016/j.jcrc.2008.07.003. PMID: 19327304
31. Romero J, Romero A, **Kirkpatrick JN**, Lange DC, Eagle KA, Baman TS. Pacemaker Reuse in a 65-Year-Old Woman in the Philippines with Severe Medical Need. *Pacing Clin Electrophysiol*. 2010 Jan;33(1):e8-9. Doi: 10.1111/j. 1540-8159.2009.02557.x. PMID: 19793365
32. Farmer SA, **Kirkpatrick JN**, Heidenreich PA, Curtis JP, Wang YF, Groeneveld PW. Ethnic and racial disparities in cardiac resynchronization therapy. *Heart Rhythm*. 2009 Mar;6(3):325-31. Doi: 10.1016/j.hrthm.2008.12.018. PMID: 19251206
33. Chirinos JA, Segers P, Gupta AK, Swillens A, Rietzschel ER, De Buyzere ML, **Kirkpatrick JN**, Gillebert TC, Wang Y, Keane MG, Townsend R, Ferrari VA, Wiegers SE, St John Sutton M.. Time-varying myocardial stress and systolic pressure-stress relationship: role in myocardial-arterial coupling in hypertension. *Circulation* 2009 Jun 2;119(21):2798-807. doi: 10.1161/CIRCULATIONAHA.108.829366. PMID: 19451350
34. Stawicki SP, Braslow BM, Panebianco NL, **Kirkpatrick JN**, Gracias VH, Hayden GE, Dean AJ. Intensivist use of hand-carried ultrasonography to measure IVC collapsibility in estimating intravascular volume status: correlations with CVP. *J Am Coll Surg*. 2009 Jul;209(1):55-61. Doi: 10.1016/j.jamcollsurg.2009.02.062. PMID: 19651063.
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in Hypertension. *Am J Physiol Heart Circ Physiol.* 2010 Feb;298(2):H320-30. doi: 10.1152/ajpheart.00334.2009. PMID: 19966060

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40. Kini V, Logani S, Ky B, Chirinos JA, Ferrari VA, St. John Sutton MG, Wiegers, **Kirkpatrick JN**. Transthoracic and Transesophageal Echocardiography for the Indication of Suspected Infective Endocarditis: Vegetations, Blood Cultures and Imaging. *J Am Soc Echocardiogr*. 2010 Apr;23(4):396-402. doi: 10.1016/j.echo.2009. PMID: 201138467
41. Testani JM, St John Sutton MG, Wiegers SE, Khera AV, Shannon RP, **Kirkpatrick JN**. Accuracy of noninvasively determined pulmonary artery systolic pressure. *Am J Cardiol.* 2010 Apr 15;105(8):1192-7. doi: 10.1016/j.amjcard.2009.11.048. PMID: 20381676
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43. Baman TS, **Kirkpatrick JN**, Romero J, Gakenheimer L, Romero A, Lange DC, Nosowsky R, Fuller K, Sison EO, Tangco RV, Abelardo NS, Samson G, Sovitch P, Machado CE, Kemp SR, Morgenstern K, Goldman EB, Oral H, Eagle KA. Pacemaker reutilization: an initiative to alleviate the burden of symptomatic bradyarrhythmia in impoverished nations around the world. *Circulation*. 2010 Oct 19;122(16):1649-56. Doi: 10.1161. PMID: 20956239
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45. **Kirkpatrick JN**, Beasley KD, Caplan AL: Death is just not what it used to be. *Camb Q* Healthc Ethics. 2010 Winter;19(1):7-16. doi: 10.1017/S096318010999020X. PMID: 20025798
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52. **Kirkpatrick JN**, Gottlieb M, Sehgal P, Patel R, Verdino R. Deactivation of Implantable Cardioverter Defibrillators in Terminal Illness and End of Life Care. *Am J Cardiol*. 2012 Jan 1;109(1):91-4. doi: 10.1016/j.amjcard.2011.08.011. PMID: 21943937
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101. Addetia K, Miyoshi T, Schreckenberg M, Blankenhagen M, Hitschrich N, Amuthan V, Citro R, Daimon M, Gutiérrez-Fajardo P, Kasliwal R, **Kirkpatrick JN,** Monaghan MJ, Muraru D, Ogunyankin KO, Park SW, Tude Rodrigues AC, Ronderos R, Sadeghpour A, Scalia G, Takeuchi M, Tsang W, Tucay ES, Zhang M, Mor-Avi V, Asch FM, Lang RM: 3D Echocardiography-Based Assessment of Left Ventricular Diastolic Function: A Report from World Alliance of Societies of Echocardiography (WASE) study. ASE, 2021.

102. Pattock A, Kim MM, Kersey C, Liu L, Kessler R, Adedipe A, **Kirkpatrick JN,** Huang G, Kwon Y: Cardiac Point-of-Care Ultrasound Publication Trends. ASE, 2021

103. Muraru D, Miyoshi T, Addetia K, Citro R, Daimon M, Desale S, Fajardo PG, Kasliwal RR, **Kirkpatrick JN,** Monaghan MJ, Ogunyankin KO, Park SW, Ronderos RE, Sadeghpour A, Scalia GM, Takeuchi M, Tsang W, Tucay ES, Tude Rodrigues AC, Vivekanandan A, Zhang Y, Blitz A, Lang RM, Asch FM, Badano LAge- and Ethnicity-Specific Normative Values of TAPSE/PASP ratio from the World Alliance of Societies of Echocardiography (WASE) Study. ASE, 2021.

17. OTHER ACADEMIC/INSTITUTIONAL APPOINTMENTS

1993-1994	Instructor/Curriculum Coordinator, Academic Curriculum Institute, Los Angeles, California
1995	Volunteer Physician, Hospital de Valle De Angeles, Honduras
1998	Volunteer Physician, Ishaka Adventist Hospital, Uganda
1999	Volunteer Physician, Hospital Albert Schweitzer, Haiti
2001	Volunteer Physician, Center for Disease Control and Bach Mai Hospital, Hanoi, Vietnam
2006-2015	Volunteer Physician, Esperanza Health Center, Philadelphia, Pennsylvania
2006-2012	Associate Fellow, Center for Bioethics
2011-2015	Associate Fellow, University of Pennsylvania Center for Behavioral Health Research

TEACHING POSITIONS

2006-2013	Fellows Echocardiography Conference: "Cardiac Masses", Cardiovascular Division of Medicine
2007-2010	Fellows Echocardiography Conference: "Septae and Shunts", Cardiovascular Division of Medicine
2007-2008	Stroke Grand Rounds: "Transesophageal Echocardiography", University of Pennsylvania Department of Neurology
2008-2010	Fellows Echocardiography Conference: "Strain", Cardiovascular Division of Medicine
2008-2015	Fellows Echocardiography Conference: "Echo Potpourri", Cardiovascular Division of Medicine

2008	"Reuse of Intracardiac Rhythm Management Devices: an Ethical Issue?" Bioethics Interest Group. University of Pennsylvania School of Medicine
2009-2015	Coordinator, Fellows Ethics Education Sessions. University of Pennsylvania Cardiovascular Division.
2009-2011	"Ethical Issues in Cardiovascular Medicine." Clinical Pastoral Care Education, Hospital of the University of Pennsylvania
2010	"Ethical Issues in Heart Failure" Ethics Grand Rounds. Hospital of the University of Pennsylvania, Department of Nursing. November 9, 2010
2010	"Reuse of Intracardiac Rhythm Management Devices." University of Pennsylvania Undergraduate Bioethics Interest Group
2011	"Cardioethics" University of Pennsylvania School of Medicine Bioethics Interest Group.
2011	"Cardiac Devices in the "Golden Years": All that Glitters" Hospital of the University of Pennsylvania Geriatrics Grand Rounds
2012	"Cardioethics: Getting to the Heart of Ethics" Department of Cardiology Grand Rounds Hospital of the University of Pennsylvania. January 26, 2012
2012	FR601 Bioethics and Professionalism 2012 "Conflicts of Interest in Clinical Practice Guidelines" February 21, 2012
2012	Empirical Bioethics Class 690 "Cardioethics" February 22, 2012
2012	"Palliative Care Issues in Cardiology: Naturally Complicated." University of Pennsylvania Interprofessional Palliative Care Seminar Series November 15, 2012
2012	Echocardiography Conference "Endocarditis"
2012	Echocardiography Conference "VAD Evaluation & Emergencies"
2012-2013	Echocardiography Conference: "RA/IVC/SVC"
2013	"New Cardiovascular Technologies and their Impact on End of Life Care Planning." Ethics Committee Educational Seminar, Hospital of the University of Pennsylvania Ethics Committee. February 7, 2013
2013	"Works in Progress" seminar. Department of Medical Ethics and Health Policy. May 1, 2013
2013	"Dilemmas of Devices: A Discussion About Pastoral Needs of Cardiac Patients and Their Families." Summer Clinical Pastoral Care Education Series, Hospital of the University of Pennsylvania
2013	"Echo and the Right Ventricle in Ventricular Assist Devices." Heart Failure Fellows Conference
2013	"Palliative Care Issues in Cardiology: Naturally Complicated." HUP Internal Medicine Resident Report. October 18, 2013
2013	"Cardiovascular Anatomy, Physiology and Pathophysiology for the Non-cardiologist." BSTA 510 Lecture: Intro to Human Health and Diseases
2014	"Size Matters: Appropriateness, Promises and Perils of Mini Echo Machines." Cardiology Grand Rounds, Cardiovascular Division, University of Pennsylvania. January 30, 2014
2014	"Ethics of Clinical Studies in Pulmonary Vascular Disease" The Alfred P. Fishman Symposium: New Treatment Approaches to Pulmonary Hypertension
2014	"Evaluation of Murmurs." Internal Medicine Resident Education Session. Hospital of the University of Pennsylvania. February 4, 2014
2014	“Empiricism in Cardioethics” Empirical Bioethics Today course lecture. School of Medicine, University of Pennsylvania. March 20, 2014
2014	"Conflicts of Interest in Clinical Practice Guidelines." FR601 Medical Student Lecture, University of Pennsylvania School of Medicine

2014	CV Pathophysiology Course, CV Physiologic Data Workshop. University of Pennsylvania School of Medicine. September 3, 2014
2015	"LVADs and Defibrillators and TAVR's, Oh My! Walking the Road with Patients who Have Implanted Cardiac Devices." Palliative Care Grand Rounds, Hospital of the University of Pennsylvania. May 19, 2015.
2015	"Delivering VAD News: Echo and VAD Emergencies." UW Fellows Didactic Conference. December 4, 2015
2016-present	Cards A/Consult Didactic Lecture Series, Presenter, University of Washington
2017	"Truth Telling in Medicine." Harborview Medical Center Ethics Rounds. January 11, 2017
2017	"Advance Directives (AD) and Goals of Care (GOC) Discussions in Heart Failure" UW Fellows Didactic Conference. February 24, 2017
2017	"Informed Consent and Truth Telling: On a 'Need to know' basis, and YOU need to know!" UW Fellows Didactic Conference. April 21, 2017
2017	"Appropriate use of Imaging for CAD", University of Washington Cardiology A/Cardiology Consult Lecture Series. May 9, 2017
2017	"Ethics of Heart Failure Management." NW Heart Failure Collaborative, Project Echo. May 17, 2017
2017	"Update on Echocardiography in Heart Failure." CME Morning Rounds, University of Washington. May 23, 2017
2017	"Echo Trends." NW Heart Failure Collaborative, Project Echo. Dec 20, 2017
2017-2018	"Cardiac Stress Testing" UW Medicine Neighborhood Clinics.

REVIEWING POSITIONS

2005-2006	Guest Editor/Perspectives in Biology and Medicine (Winter Edition)
2006-	Reviewer/Echocardiography
2007	Reviewer/Perspectives on Biology and Medicine
2007	Reviewer/Bioinformatics and Genomics
2007-	Reviewer/Journal of the American Society of Echocardiography
2008-	Reviewer/American Journal of Cardiology
2008-	Reviewer/Journal of Cardiac Failure
2009	Reviewer/European Journal of Heart Failure
2010	Reviewer/Heart Rhythm
2010-	Reviewer/Circulation-Heart Failure
2010	Reviewer/Journal of Clinical Ethics
2010-	Reviewer/Annals of Internal Medicine
2012-2013	Guest Editor/World Journal for Pediatric and Congenital Heart Surgery. Proceedings of Symposium on Ethical Challenges of Congenital Heart Disease, January 2013
2014-	Reviewer/Journal of the American College of Cardiology-Imaging
2014-	Reviewer/JAMA-Internal Medicine
2014-	Reviewer/Journal of Palliative Care
2017-	Reviewer/Circulation-Quality of Care and Outcomes

LECTURE PRESENTATIONS

Apr, 2003	"Clinical Ethics and Heart Failure: To Boldly Go Where…" Association of Black Cardiologists Heart Failure Symposium, Richmond, VA
Mar, 2004	"Ethical Analysis in Clinical Electrophysiology: A Voyage Beyond 'Can'." South Atlantic Society of Electrophysiology for Allied Professionals annual meeting, Myrtle Beach, SC

Sep, 2005	"Sherlockian Conundrums: 'Atypical Presentations of Cardiovascular and Respiratory Diseases' or 'Never Say, Elementary…'" Midwestern University, Downer's Grove, IL
Jun, 2006	"Isolated Diastolic Dysfunction and Torsional Deformation." American Society of Echocardiography Scientific Sessions, Baltimore, MD
Jun, 2006	"Echocardiographic Contrast Perfusion in the Differential Diagnosis of Cardiac Masses." American Society of Echocardiography Scientific Sessions, Baltimore, MD
Jun, 2007	"Case of Echo and Heart Transplant." American Society of Echocardiography Annual Scientific Sessions, Seattle, WA
Jun, 2007	"A View from the Apex: Aneurysms/Thrombi." American Society of Echocardiography Annual Scientific Sessions, Seattle, WA
Jan, 2008	"Emerging Emergencies of Ethics and Implanted Cardiac Devices." Cooper University Hospital, UMDNJ Medical Center, Department of Emergency Medicine Grand Rounds, Camden, NJ
Mar, 2008	"Echo for the Masses, Perfusion the Differential Diagnosis." 24th Annual International Conference on Recent Advances in Echocardiography and Allied Techniques, Chicago, IL
May, 2008	"Outcomes Choices Framed in an Ethics Context." American Heart Association Conference: ECC Outcomes Consensus Conference. Washington, DC
Jun, 2008	"Vena Contracta." American Society of Echocardiography Annual Scientific Sessions, Toronto, ON, Canada
Nov, 2008	"A Tragic Case of Echo and Occam's Razor." 18th Annual International Conference on Echocardiography and Allied Techniques: Case Studies and Recent Advances in Echocardiography, New Orleans, LA
Apr, 2009	"Considerations in Special Populations with Cardiovascular Disease." American College of Physicians Scientific Sessions, Philadelphia, PA
May, 2009	Panel discussant: "Establishing an International Emergency Cardiopulmonary Bypass Network." International ECPB Network Conference. Philadelphia, PA
Jun, 2009	"Aortic Stenosis with Normal Ejection Fraction". American Society of Echocardiography Scientific Sessions, Washington, DC
Sep, 2009	"Looking out for the Patient--Ethics and Implanted Cardiac Devices." 15th Annual Workshop of the South Atlantic Society of Electrophysiology for Allied Health Professionals, Myrtle Beach, SC
Jan, 2010	"Reuse of Pacemaker/Defibrillators in Developing Nations." University of Pennsylvania Penn Undergraduate Bioethics Interest Group, Philadelphia, PA
Mar, 2010	"To the OR or not to the OR?" 26th Annual International Conference on Recent Advances in Echocardiography and Allied Techniques, Atlanta, GA
Jun, 2010	"Overview of Echo and Ventricular Assist Devices." American Society of Echocardiography Scientific Sessions, San Diego, CA
Jun, 2010	"The Right Atrium-The Forgotten Chamber." American Society of Echocardiography Scientific Sessions, San Diego, CA
Nov, 2010	"3D for 3V" 20th Annual International Conference on Echocardiography and Allied Technique, Chicago, IL
Mar, 2011	"Echo and Ventricular Assist Devices: Novel Applications of Emerging Imaging Modalities" Keith Hackney Memorial Lecture, Delaware Valley Echo Society, Philadelphia, PA
May, 2011	"Device Reprocessing and Re-Implantation: Humanitarian Considerations and Potential for Cost Containment." Heart Rhythm 2011. 32nd Annual Scientific Sessions, San Francisco, CA

Jun, 2011	"Mini Case Presentation on the Discussion of Quality Considerations." American Society of Echocardiography Scientific Sessions, Montreal, Quebec, Canada
Jun, 2011	"TR and PR - Where Are We?" American Society of Echocardiography Scientific Sessions, Montreal, Quebec, Canada
Jun, 2011	"Preliminary Reports - When and Why." American Society of Echocardiography Scientific Sessions, Montreal, Quebec, Canada
Sep, 2011	"End of life: when the heart is taken out of the equation." Heart Failure Society of American Scientific Meeting, Boston, MA
Sep, 2011	"Changing Goals of Care in Advanced Disease" 15th Annual Scientific Meeting Heart Failure Society of America, Boston, MA
Nov, 2011	"Hemodynamic Measurements by Echocardiography and Current Dynamics in 'Cardioethics': Some Things Always Change." Mercy Health System Medical Grand Rounds Program, Conshohocken, PA
Nov, 2011	"A Different Way of "Going Green": Reuse of Pacemakers" MacLean Conference, MacLean Center for Clinical Medical Ethics, Chicago, IL
Feb, 2012	"Conflicts of Interest in Cardiovascular Clinical Practice Guidelines" Abington Memorial Hospital Medical Grand Rounds, Abington, PA
Mar, 2012	"Interesting Case Studies" 28th Annual International Conference on Recent Advances In Echocardiography and Allied Techniques, Chicago, IL
May, 2012	"Pre-implant Ethical Dilemmas in Mechanical Circulatory Support." Program for Biomedical Ethics Seminar Series. Yale-New Haven Hospital. New Haven, CT
Jul, 2012	"Heart Failure: Transplant and Left Ventricular Assist Devices (LVAD) Can We Diagnose Transplant Rejection?" American Society Echocardiography 2012 Scientific Sessions, National Harbor, MD
Jul, 2012	"Contrast Fundamentals Identification of Masses" American Society of Echocardiography 2012 Scientific Sessions. National Harbor, MD.
Jul, 2012	"Diastole - Relax! Volume Status - Is Echo a Non-Invasive Swan?" American Society of Echocardiography 2012 Scientific Sessions. National Harbor, MD.
Sep, 2012	"Cardiac Advanced Directives: How hard it can be?" Georgia Health Sciences University 2012 annual cardiac conference Registered Nurses symposium, Atlanta, GA
Sep, 2012	"Resuscitating Ethics in Cardiac Arrest" Georgia Health Sciences University 2012 Annual Cardiac Conference, Atlanta, GA.
Sep, 2012	"Destination Ethics: Conundrums in LVAD-DT" Georgia Health Sciences University 2012 Annual Cardiac Conference, Atlanta, GA
Sep, 2012	"Symptom Burden and Palliation" Heart Failure Society of America 16th Annual Scientific Meeting, Seattle, WA
Jan, 2013	"The Good, the VAD and the Echo: Imaging of Mechanical Circulatory Support" Cardiology Grand Rounds, Temple University, Philadelphia, PA. 1/25/2013
Jan, 2013	"The Good, the VAD and the Echo: Imaging Mechanical Circulatory Support" Penn Presbyterian Medical Center Cardiology Grand Rounds, Philadelphia, PA. 1/17/2013
Mar, 2013	"Cardiomyopathy After Pregnancy or...Got LVAD?" American College of Cardiology Annual Scientific Session, San Francisco, CA 3/9-11/2013
Mar, 2013	"Mysterious Ways: God's Lessons for a Cardiologist through Heart Surgery" Medical Campus Outreach, Philadelphia, PA March 3, 2013.
Apr, 2013	"Hand Carried Cardiac Ultrasound" Cardiovascular Centre at Hue Central Hospital, Hue, Vietnam. April 15, 2013.
May, 2013	"EF Roulette: Comparing Different Imaging Modalities in Determining Left Ventricular Ejection Fraction." Heart Rhythm Society Scientific Sessions, May 10, 2013, Denver, CO

Jun, 2013	"RV Function on LVAD Support: What does the Long Term Look Like?" Gordon Research Conference: Assisted Circulation. Renaissance Tuscany Il Choco Resort in Lucca (Barge) Italy. June 25, 2013.
Jun, 2013	"The importance of the RV in VAD patients" American Society of Echocardiography Scientific Sessions 2013 June 30, 2013, Minneapolis, MN
Jul, 2013	"Echo Feature of LVADs/Impalas: How and What to Assess" American Society of Echocardiography Scientific Sessions 2013 July 1, 2013, Minneapolis, MN
Sep, 2013	"Transitions", Christian Medical and Dental Association/Medical Campus Outreach Interned Fall retreat for Philadelphia Health Sciences Schools, Drexel College of Medicine, Philadelphia, PA
Sep, 2013	"Legal Foundations of Autonomy and Shared Decision-Making" Promoting Patient-Centered Care: Challenges to Autonomy and Justice in a Technological Era. Heart Failure Society of America 2013 Scientific Sessions, Orlando, FL September 22-25, 2013
Oct, 2013	"Ethics ICU/Devices/ECMO and Discontinuation of Care", Georgia Health Sciences University Annual Cardiac Conference, Atlanta, GA
Nov, 2013	"Ethical Issues at the end of life end of life management of implantable cardiac devices" 25th Annual MacLean Center Conference, MacLean Center for Clinical Medical Ethics, University of Chicago, Chicago, Il
Nov, 2013	"Portrait of an LVAD: Imaging in Mechanical Circulatory Support" Cardiology Grand Rounds, University of Chicago, Chicago, IL
Jan, 2014	"Escape from the Appropriateness Police" Cardiovascular Institute Echocardiography Update, Philadelphia, PA Jan 12, 2014.
Jan, 2014	"Portrait of an LVAD", Cardiovascular Imaging Rounds, Jan 13, 2014, Brigham and Women's Hospital, Boston, MA
Mar, 2014	"Pocket-size Echo: The Good and the Bad of Being More Than Just an Ultrasonographic Stethoscope." American College of Cardiology 2014, Scientific Sessions, Joint Symposium of the Italian and Pennsylvania Chapters of the American College Cardiology.
Apr, 2014	"Ethics of Clinical Studies in Pulmonary Vascular Disease." The Alfred P. Fishman Symposium: New Treatment Approaches to Pulmonary Hypertension, Philadelphia, PA
Apr, 2014	"More than Plumbing and Electricity: Ethics and Meaning in Implantable Devices". Transplant Grand Rounds, Mayo Clinic, Rochester, MN
Nov, 2014	“Death is not what it used to be.” 26th Annual MacLean Center Conference, MacLean Center for Clinical Medical Ethics, University of Chicago, Chicago, Il
Jun, 2014	"The Sunshine Act and Handing of Industry Relationships." American Society of Echocardiography Scientific Sessions, Portland, OR
Jul, 2014	"When to Introduce Palliative Care" Debate. American Association of Heart Failure Nurses. Webinar Session, University of Pennsylvania Healthcare System.
Apr, 2015	“Cardiac Palliative Care: Not so New horizons” Abington Hospital Grand Rounds, Abington, PA
May, 2015	“Last exit off the cardiac freeway: ethical considerations in palliative care and cardiovascular implantable electronic devices", MacLean Center for Clinical Medical Ethics End of Life Seminar Series, University of Chicago, Chicago, IL
Jun, 2015	"When is a ramp necessary?" American Society of Echocardiography Scientific Sessions, Boston, MA
Jul, 2015	“Cardiac Devices and Ethical and Legal Implications for the Determination of Death.” International Academy of Law and Mental Health, Vienna, Austria

Aug, 2015	"Focused Cardiac Ultrasound: Ready for Vietnam?" Vietnam National Heart Institute-American Society of Echocardiography Symposium, Hanoi, Vietnam
Aug, 2015	"Hemodynamic Measurements by Echocardiography." Vietnam National Heart Institute-American Society of Echocardiography Symposium, Hanoi, Vietnam
Aug, 2015	"Research Ethics." Bach Mai Hospital, Hanoi, Vietnam
Nov, 2015	"Imaging in the HVAD patient" University of Washington HeartWare Training.
Apr, 2016	"An Older Adult with Advanced Heart Failure, Multiple Chronic Conditions and Frailty" American College of Cardiology Scientific Sessions 2016, Chicago, IL
May, 2016	"Imaging in the HVAD patient" University of Washington HeartWare Training. Seattle, WA
Jun, 2016	"How and when to discuss device deactivation" 26th International Symposium on Congenital Heart Disease in the Adult: Innovation Past and Present, Skamania, WA
Jun, 2016	"Predicting Right Ventricular Failure: 2D? 3D? Strain?" American Society of Echocardiography Scientific Sessions, Seattle, WA
Jun, 2016	Is This Right Ventricle Good Enough to Support An LVAD? American Society of Echocardiography Scientific Sessions, Seattle, WA
Jun, 2016	Hanoi, Vietnam: Effect on the Delivery of Healthcare. American Society of Echocardiography Scientific Sessions, Seattle, WA
Jun, 2016	"Truth Telling in Practice" Medical Ethics in the 21st Century: A Practical Skill-Building Approach to Ethical Reasoning in Healthcare" Virginia Mason Clinic, Seattle, WA
Jun, 2016	"Mechanical Circulatory Support Imaging Guidelines: The What, the How and the Why of performing really VAD Echocardiography" Delaware Valley Echo Society Meeting, Philadelphia, PA
Jun, 2016	"Speed Change Echocardiography" Multimodality Imaging Conference, University of Pennsylvania, Philadelphia, PA
Aug, 2016	"How To: Having Tough Discussions with Patients and Families—Critical Conversations" Panelist, Heart Failure Society of America Scientific Sessions, Orlando, FL
Sept, 2016	"Impact of Symptom Burden and Episodic Distress" Heart Failure Society of America Scientific Sessions, Orlando, FL
Oct, 2016	"Imaging in the HVAD Patient" University of Washington HeartWare Training. Seattle, WA
Mar, 2017	"Palliative Care along the VAD Journey." INTERMACS 11th Annual Meeting and Scientific Sessions, Atlanta, GA
Apr, 2017	"Imaging in the HVAD Patient" University of Washington HeartWare Training. Seattle, WA
Jul, 2017	"Ethical Aspects of Withdrawing Implantable Cardioverter-Defibrillator and Ventricular Assist Device Support from Patients Approaching Death" International Congress on Academy of Law and Mental Health, Prague
Sept, 2017	"Sexuality and Intimacy in Patients with LVADs and their Partners: Uncovering the Un-discussed Facts", University of Washington Cardiovascular Grand Rounds, Seattle, WA
Oct, 2017	"Should we Still Assess Dyssynchorony?" Vietnam National Heart Association National Scientific Meeting 2017 Updates in Management of Heart Failure, Thanh Hoa City, Vietnam
Oct, 2017	"Roles of Stress Echocardiography in Assessment of Patients with Valvular Heart Diseases" Vietnam National Heart Association National Scientific Meeting 2017 Updates in Management of Heart Failure, Thanh Hoa City, Vietnam

Oct, 2017	"Quality in Heart Failure Echocardiography" Vietnam National Heart Association National Scientific Meeting 2017 Updates in Management of Heart Failure, Thanh Hoa City, Vietnam
Nov, 2017	"The role of ultrasound imaging in the assessment of LVAD, Impella and other circulatory support devices." American Heart Association Scientific Sessions, Anaheim, CA
June 2018	"Ethical Challenges in the Practice of Echocardiography: What is Right and How Do We Do It?" Inaugural Richard E. Kerber Ethics/Humanitarian Lecture, ASE, Nashville, TN
July 2018-19	"Negotiating Autonomy and Beneficence in Clinical Care", Annual Summer Seminar in Healthcare Ethics, Seattle, WA
Oct 2018	"Quality in Echocardiography" Vietnam National Heart Association National Scientific Meeting, Da Nang, Vietnam
Oct 2018	"Perspectives on the Right Ventricle: Structural and Functional Assessment" Vietnam National Heart Association National Scientific Meeting, Da Nang, Vietnam
July, 2019	"Cardiac Devices: The Meaning of the Machinery of Life-Prolongation" International Congress on Law and Mental Health, Rome, Italy
July, 2019	"Ethics, Humanities, and the Future of Mechanical Circulatory Support" International Congress on Law and Mental Health, Rome, Italy
Sept, 2019	"Cardioethics: Cases from the trenches" University of Washington Cardiovascular and Bioethics Grand Grand Rounds, Seattle, WA
Nov, 2019	"3D echocardiography in imaging the tricuspid valve" Vietnam National Heart Association/Vietnam National Heart Institute Congress, Hanoi, Vietnam
Nov, 2019	"HFpEF: What are we are looking for?" Vietnam National Heart Association/Vietnam National Heart Institute Congress, Hanoi, Vietnam
Nov, 2019	"POCUS is coming" for CVD screening" Vietnam National Heart Association/Vietnam National Heart Institute Congress, Hanoi, Vietnam
Nov, 2019	"Echocardiography and Cardiac Masses" Bach Mai Hospital, Hanoi, Vietnam
Nov, 2019	"Perspectives on the Right Ventricle: Structural and Functional Assessment" Bach Mai Hospital, Hanoi, Vietnam
Feb, 2020	"Promoting Quality in Hand-held Cardiac Ultrasound - What is the Future?" American College of Cardiology Cardiovascular Summit
Apr, 2020	Disability Ethics, UW LEND Fellows Conference, Seattle, WA
Apr, 2020	COVID-19 and Echocardiography: Insights from the Frontlines. Brigham and Women's Hospital Imaging Rounds
Apr 2020	Role of Multimodality Imaging in Diagnosis and Management in Patients With COVID-19. Webinar Session, American College of Cardiology
Apr, 2020	Practice Made Perfect: Addressing COVID-19 While Ensuring the Safety and Well-Being of our Geriatric Patients (Part 1). Bailey, A, **Kirkpatrick, JN**, Maurer, MS, Orr, N
May, 2020	Practice Made Perfect: Addressing COVID-19 While Ensuring the Safety and Well-Being of our Geriatric Patients (Part 2). Bailey, A, **Kirkpatrick, JN**, Maurer, MS, Orr, N
June, 2020	Echo is the first choice for LAA occlusion planning Gladiators arena: Great debates in cardiovascular CT (and echo). Society of Cardiac Computed Tomography Scientific Sessions
June, 2020	Multimodality Imaging in Acute and Chronic COVID19: Echocardiography First. Society of Cardiac Computed Tomography Scientific Sessions
July, 2020	Ethical Dilemmas Surrounding Care for Patients with COVID-19. Chief of Medicine Rounds at the University of Washington Medical Center.

Aug, 2020	Mechanical Circulatory Support for the Right Ventricle. American Society of Echocardiography Scientific Sessions
Aug, 2020	Point of Care US training for the clinician. American Society of Echocardiography Scientific Sessions
Sept, 2020	Research Misconduct. UW Cardiology Grand Rounds
Oct, 2020	HFrEF: Where should be going in 2020? Vietnam National Heart Association Congress
Oct, 2020	The use of POCUS in different clinical settings. Vietnam National Heart Association Congress
Oct, 2020	Why we all need more strain in life. Vietnam National Heart Association Congress

ORGANIZING ROLES IN SCIENTIFIC MEETINGS

Nov, 2008	Chair/Moderator, Abstract Session of the American Heart Association Scientific Sessions, New Orleans, LA
Jun, 2009	Chair/Moderator. Valve Disease computer tutorial. American Society of Echocardiography Scientific Sessions, Washington, DC
Jun, 2009	Chair/moderator. Moderated Oral Abstract Poster Session. American Society of Echocardiography Scientific Sessions, Washington, DC
Mar, 2010	Faculty discussion facilitator, poster session. American College of Cardiology Scientific Sessions, Atlanta, GA
Jun, 2010	Moderator, Moderated Oral Poster Session, Quality, Appropriateness, Lab Accreditation, Ergonomics, and Outcomes Research. American Society of Echocardiography Scientific Sessions, San Diego, CA
Jun, 2011	Abstract Reviewer. American Society of Echocardiography Scientific Sessions, Montreal, Quebec, Canada
Jun, 2011	Co-chair How to Put the "Q" in Quality American Society of Echocardiography 22nd Annual Scientific Sessions, Montreal, Quebec, Canada
Jun, 2011	Co-chair, Ethics in Echo. American Society of Echocardiography 22nd Annual Scientific Sessions, Montreal, Quebec, Canada
Jun, 2012	Abstract Reviewer. American Society of Echocardiography Scientific Sessions, National Harbor, Maryland
Sep, 2012	Moderator, Management in Nursing Homes. Heart Failure Society of America 16th Annual Scientific Meeting, Washington State Convention Center, Seattle WA
Jun, 2013	Moderator: "Echo in Patients with VADs" American Society of Echocardiography Scientific Sessions 2013, Minneapolis, MN
Jun, 2013	Abstract Reviewer. American Society of Echocardiography Scientific Sessions, Minneapolis, MN
Jun, 2014	Abstract Reviewer. American Society of Echocardiography Scientific Sessions, Portland, OR
Jun, 2015	Abstract Reviewer. American Society of Echocardiography Scientific Sessions, Boston, MA
Jun, 2016	Moderator: “ASE Foundation Global Initiatives: Humanitarian Missions in Argentina and Vietnam.” American Society of Echocardiography Scientific Sessions, Seattle, WA
Jun, 2016	Abstract Reviewer. American Society of Echocardiography Scientific Sessions, Seattle, WA
Mar, 2017	Organizer and Moderator, “Palliative Care for the 99%”, Intensive, American College of Cardiology scientific Sessions 2017, Washington, DC

2015-present	Abstract Reviewer. American Society of Echocardiography Scientific Sessions
2016-present	Moderator. American Society of Echocardiography Scientific Sessions
Oct, 2018	Moderator. Vietnam National Heart Association Scientific Sessions, Da Nang, Vietnam
Nov, 2019	Moderator. Vietnam National Heart Association/Vietnam National Heart Institute Congress, Hanoi, Vietnam
Mar, 2020	Committee Member: ACC.20/World Congress of Cardiology Program, Cardiac Imaging (Echocardiography, Nuclear, PET, MR & CT)
Aug, 2020	Committee Member: ASE Scientific Program
Aug 2020	Senior Co-Chair, Episodes of Care #3, ASE Scientific Sessions 2020
May, 2020	Committee Member: ACC.21 Program, Cardiac Imaging (Echocardiography, Nuclear, PET, MR & CT)
Oct, 2020	Moderator and co-chair, POCUS training village. Vietnam National Heart Association Virtual Congress
Oct, 2020	Panelist, Cardiology in 2020: Challenges and Opportunities. Vietnam National Heart Association Virtual Congress
Oct, 2020	Chairperson: Future of Echocardiography. Vietnam National Heart Association Virtual Congress
Oct, 2020	Frailty and Geriatric Considerations. Great Wall International Congress of Cardiology (Virtual)
May, 2020	Abstract Reviewer, ACC.21
June, 2021	Committee Member and Chair of Function Track, ASE Scientific Sessions Program 2021
June, 2021	Abstract co-chair, ASE Scientific Sessions 2021

Applicant Name	James Kirkpatrick
Address	1959 Pacific St
	Seattle, WA 98125
	Click here to enter text.

1. Business Activities

(a) If you or a member of your household was ***an officer or director of a business*** during the immediately preceding calendar year and the current year to date, provide the following:

Title	Business Name & Address	Business Type
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) If you or a member of your household ***did business under an assumed business name*** during the immediately preceding calendar year or the current year to date, provide the following information:

Business Name	Business Address	Business Type
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

2. Honorarium

If you ***received an honorarium of more than $100*** during the immediately preceding calendar year and the current year to date, list all such honoraria:

Received From	Organization Address	Service Performed
Cardiovascular Institute of Philadelphia	Cardiovascular Institute of Philadelphia P.O. Box 56598 Philadelphia, PA 19111 www.cviphiladelphia.org	Educational lecture
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

3. Sources of Income

(a) Identify ***income source(s) that contributed 10% or more of the combined total gross household income*** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

Source Name & Address	Received By	Source Type
University of Washington	self	salary
Hope Central Pediatrics	wife	salary

Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.
Click here to enter text.
Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.
Click here to enter text.
Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household ***shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist***, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

Lobbyist Name	Business Name	Type Business Shared
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
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Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (***not amounts***) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

Income Source	Address	Description of Income Source
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

Business Name	Business Address	Description of Business
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each ***person for whom you performed a service for a fee of more than $1,000*** in the immediate preceding calendar year or the current year to date.

Name	Description of Service
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name James Kirkpatrick

Check One: ☐ Committee Member ☐ Subgroup Member ☐ Contractor

[redacted]

Signature

7/27/24

Date

Washington State Health Care Authority

Agency medical director comments

Noninvasive Cardiac Imaging: Re-review

Christopher Chen, MD, MBA
Medical Director for Medicaid
WA Health Care Authority

Linda Liu, MD
HCA CQCT Policy Fellow
UW Harborview Inpatient Chief Resident

November 5, 2021

1

Washington State Health Care Authority

Noninvasive Cardiac Imaging Background

- Evaluate heart function and anatomy under stress
- Heterogeneous topic
  - Indications
  - Settings
  - Methods of risk stratification variable

Indications
Coronary Artery Disease (CAD) – Angina – Acute Coronary Syndrome – Known CAD with changing symptoms – Prior revascularization
Valvular Heart Disease
Cardiomyopathy
Arrhythmias
Preoperative evaluation

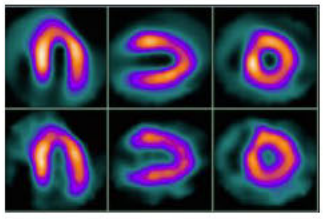
2

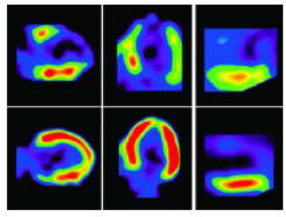
2

Washington State Health Care Authority

Stress modalities

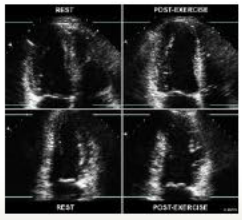
SPECT

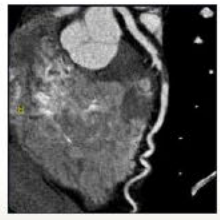




PET

Echo





CCTA

3

3

Washington State Health Care Authority

Noninvasive Cardiac Imaging: Background

- Risk of Coronary artery disease for symptomatic adults
  - Low
  - Intermediate
  - High
- Multitude of scoring systems
  - Framingham Global Risk assessment scoring: age, sex, total cholesterol, HDL cholesterol, smoking, SBP, DM
  - SCORE: age, set, total-HDL cholesterol ratio, smoking, SBP
  - PROCAM (men): Age, LDL, HDL cholesterol, smoking, SBP, family history, diabetes, triglycerides
  - Reynolds (women): Age, HbA1C, DM, smoking, SBP, total/HDL cholesterol, CRP, parental history of MI at <60 years of age
  - TIMI

*2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults," JACC 56 25, 350-103, 2010.

4

4

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Previous HTCC decisions

- No prior decisions on stress echocardiogram
- 2013: Nuclear imaging including PET/SPECT
  - Included asymptomatic individuals
- 2009: CCTA (no FFR)
- Cardiac magnetic resonance angiography (cMRA) to be presented November 19; no prior decisions

5

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Washington State Health Care Authority

Previous HTCC Decision: SPECT

- Cardiac Nuclear Imaging is a covered benefit for :
  - For patients with symptoms of myocardial ischemia (symptomatic) who are:
    - At high risk of coronary artery disease (CAD), or
    - At low to intermediate risk of CAD, and
      - Have abnormal/indeterminate exercise treadmill test (ETT), or
      - Unable to perform ETT, or
      - Electrocardiogram (ECG) abnormality that prevents accurate interpretation of ETT.
  - For patients with known CAD, monitoring:
    - Changes in symptoms
- Cardiac Nuclear Imaging is not a covered benefit for:
  - Asymptomatic patients
    - Does not apply to pre-operative evaluation of patients undergoing high-risk non-cardiac surgery or patients who have undergone cardiac transplant.
  - Patients with known CAD and no changes in symptoms

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Washington State Health Care Authority

Previous HTCC Decision: PET

- Covered under the same conditions as SPECT when:
  - SPECT is not technically feasible; or
  - SPECT is inconclusive

7

Washington State Health Care Authority

Previous HTCC Decision: CCTA

- Covered when:
  - 1) Patients with low to intermediate risk of coronary artery disease;
  - 2) For investigation of acute chest pain in an emergency department or hospital setting; and
  - 3) Using Computed Tomography machines with 64-slice or better capability.
- Not covered when:
  - Patients who are asymptomatic or at high risk of coronary artery disease;
  - CCTA used for coronary artery disease investigation outside of the emergency department or hospital setting; and
  - CT scanners that use lower than 64- slice technology.

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Washington State Health Care Authority

Noninvasive Cardiac Imaging: HTCC Re-review Rationale

- Selected on the basis of **high prevalence** of coronary artery disease and high degree of **clinical variation** in stress test selection
- High **cost and utilization** of noninvasive cardiac imaging
- Stakeholder feedback on prior authorization for noninvasive cardiac imaging
- Further development of **evidence base** since last reviews

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Washington State Health Care Authority

Scope of discussion today

In scope	Out of scope/not reviewed
· Adult patients (≥18 years of age) with symptoms of **suspected (previously undiagnosed) CAD** who present with: · **Stable** (nonemergent) **typical or atypical symptoms suspicious** for CAD · **Suspected acute coronary syndrome** (ACS) in emergency departments. · **Symptomatic adults with known/established CAD** including those who have had prior MI and/or revascularization.	· Asymptomatic · Pre-op · Cardiac Transplant · Patients with STEMI · Assessment of myocardial viability prior to revascularization for individuals with LV dysfunction · Patients presenting for evaluation of cardiac pathologies other than CAD (e.g., congenital abnormalities, valvular disease, evaluation of cardiomyopathy etiology, CHF)

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Agency medical director concerns - overall

Safety = Low

Efficacy = Medium

Cost = High

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Washington State Health Care Authority

Key Questions

- What is the comparative effectiveness of noninvasive cardiac anatomic or functional imaging modalities (CCTA, stress nuclear imaging, stress echocardiography)...
  - In leading to **improved clinical outcomes** (e g., MI, mortality)?
  - With respect to **clinical decision-making including additional testing and treatments**?
  - With regard to **harms or adverse events** which may result directly from testing or additional, downstream testing?
- Does effectiveness (in terms of clinical outcomes) or safety differ in **special populations** (e.g., women, those with comorbidities, the elderly) from noninvasive cardiac anatomic or functional imaging (CCTA, stress nuclear imaging, stress echocardiography)?
- What is the **cost-effectiveness** of CCTA, stress nuclear imaging and stress echocardiography for clinical outcomes?

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Washington State Health Care Authority

Evidence Considerations

- Significant heterogeneity in:
  - Comparators
  - Definitions of risk
  - Populations studied

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Safety

- Despite being a heterogeneous group of diagnostics, **generally non-invasive cardiac imaging tests are safe** with rare occurrence of life threatening adverse events
- **Stress agents** may be associated with transient side effects; **contrast agent** related adverse events and allergic reactions are rare
- **Radiation exposure** is higher for SPECT than CCTA; however cumulative radiation may be higher with CCTA as index, and repeated testing may subject patients to greater exposure
- For CCTA, **incidental findings** are common that may merit further workup

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Washington State Health Care Authority

Efficacy

- **Stress echo compared to exercise ECG**
  - Insufficient evidence re: risk of MI, all cause mortality, and cardiac mortality
  - In stable patients with suspected CAD, associated with reduced risk of ICA and downstream NIT (SOE Low)
- **SPECT compared to stress echo**
  - No different in risk of MI, all cause mortality, or cardiac mortality (SOE low-insufficient)
  - No difference in risk of revascularization or hospitalization (SOE moderate)
- **PET compared to SPECT**
  - No difference in clinical outcomes including MI, all-cause mortality (SOE insufficient)

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Efficacy (continued)

- **CCTA**
  - High NPV in low risk patients for CAD rule out
  - No clear difference on clinical outcomes, several RCTs with similar outcomes/cost of care/LOS (PROMISE, BEACON, ROMICAT-II)
    - SCOT-Heart: Possible added benefit in stable chest pain reducing non-fatal MIs and deaths from CAD, but mostly ETTs in the control arm
    - In symptomatic outpatients, CCTA vs function testing leads to ? higher ICA referral and revascularization with increased radiation
  - FFR: PLATFORM study; FFR CT approximates invasive FFR, may lead to decreased ICA

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Cost

- Only a few studies compared one specific test directly over another; most compared testing strategies and results were mixed, with **many limitations**
- For **stable outpatients**, two systematic reviews suggesting that stress echo may be more cost-effective than SPECT in patients with low to intermediate risk
- In **patients with suspected ACS** in the ED, CCTA was found to be the more cost-effective approach in some studies

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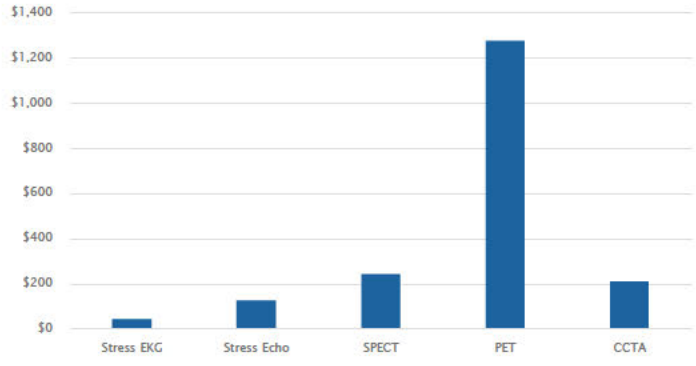
Medicaid FFS Non-invasive Cardiac Imaging Reimbursement



**Reimbursement does not include codes for radiopharmaceuticals or drugs administered during the stress test or added costs of stress test codes, and are based on non-facility costs. Estimated facility costs are higher.

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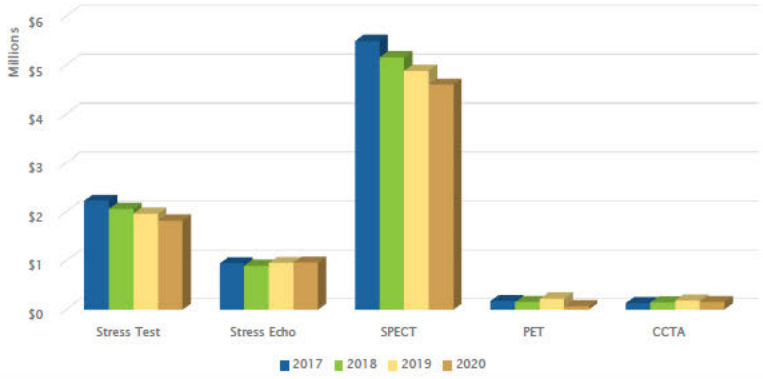
Washington State Health Care Authority

Non-Invasive Cardiac Imaging Expenditures



**Expenditures do not include codes for radiopharmaceuticals or drugs administered during the stress test. PET codes revised in 2020 were not included in utilization data.

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Washington State Health Care Authority

Current Coverage: Stress echo

- AIM: generally covered for symptomatic individuals*
  - Suspected CAD in symptomatic patients who have not had evaluation of CAD within preceding 60 days
  - Known coronary artery disease in patients who have new or worsening symptoms
- WA Medicaid FFS: No current clinical policy
- Other payers:
  - Medicare LCD: for patients with ECG abnormality, prior equivocal stress ECG, or history of posterior wall MI
    - Not covered if incremental information is of no clinical relevance or is performed too frequently

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval, pulmonary hypertension, HOCM

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Washington State Health Care Authority

Current Coverage: SPECT

- AIM:
  - Suspected CAD in symptomatic patients who have not had evaluation of CAD in preceding 60 days with intermediate to high risk of CAD or commonly coexisting chronic condition (AAA, PVD, CVA, CKD) or high risk occupation
  - Known CAD in patients who have new or worsening cardiac symptoms
- WA Medicaid: follows 2013 HTCC
- Other payers:
  - Medicare LCD: requires documentation of medical necessity per AUC or similar standard

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval

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Washington State Health Care Authority

Current Coverage: PET

- AIM:
  - Appropriate as the initial stress imaging test for suspected or established CAD in patients who have a relative contraindication to conventional nuclear perfusion imaging and/or a contraindication to exercise stress testing
- WA Medicaid: follows 2013 HTCC
- Other payers:
  - Aetna: PET is used in place of SPECT in those who are not candidates for SPECT, or used following an inconclusive SPECT scan

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval

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Washington State Health Care Authority

Current Coverage: CCTA

- AIM:
  - Suspected CAD in symptomatic patients as index study or who have had abnormal exercise EKG, equivocal or abnormal MPI or stress echo
- WA Medicaid: follows 2009 HTCC
- Other payers:
  - Aetna: Symptomatic patients with low-intermediate pre-test probability of CAD, with or without a positive stress test
  - Medicare LCD: as an alternative to invasive angiography and stress testing; not medically necessary if pre-test evaluation indicates that patient would require ICA for further diagnosis or for therapeutic intervention

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval

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ACC 2013 Multimodality Appropriate Use Criteria for Stable Ischemic Heart Disease

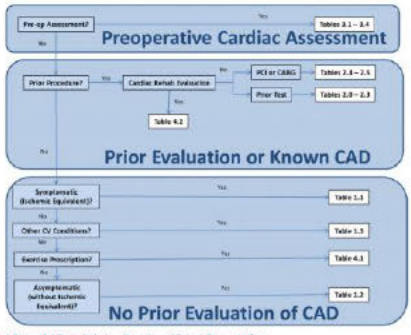

Figure 1. Hierarchy of Potential Test Ordering Based on Clinical Presentation

For those patients who may be classified into more than 1 of the clinical indication tables and/or algorithms, this flowchart places clinical conditions into a hierarchy to aid in assessing appropriateness. Patients sent for testing for purposes of pre-operative cardiac assessment who are rated Rarely Appropriate for testing based on surgery alone may be considered for testing for other reasons (e.g., symptomatic). CABG = coronary artery bypass graft; CAD = coronary artery disease; CV = cardiovascular; PCI = percutaneous coronary intervention.

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ACC 2013 AUC– no known CAD

Table 1.1. Symptomatic

Refer to pages 16 and 17 for relevant definitions, in particular Table A and text for age, sex, symptom presentation, and risk factors relevant to each pre-test probability category								
Indication Text		**Exercise ECG**	**Stress RNI**	**Stress Echo**	**Stress CMR**	**Calcium Scoring**	**CCTA**	**Invasive Coronary Angiography**
1.	• Low pre-test probability of CAD • ECG interpretable AND able to exercise	A	R	M	R	R	R	R
2.	• Low pre-test probability of CAD • ECG uninterpretable OR unable to exercise		A	A	M	R	M	R
3.	• Intermediate pre-test probability of CAD • ECG interpretable AND able to exercise	A	A	A	M	R	M	R
4.	• Intermediate pre-test probability of CAD • ECG uninterpretable OR unable to exercise		A	A	A	R	A	M
5.	• High pre-test probability of CAD ECG interpretable AND able to exercise	M	A	A	A	R	M	A
6.	• High pre-test probability of CAD • ECG uninterpretable OR unable to exercise		A	A	A	R	M	A

Appropriate Use Key: A = Appropriate; M = May Be Appropriate; R = Rarely Appropriate.
A = Appropriate; CAD = coronary artery disease; CCTA = coronary computed tomography angiography; CMR = cardiac magnetic resonance; ECG = electrocardiogram; Echo = echocardiography; M = May Be Appropriate; R = Rarely Appropriate; RNI = radionuclide imaging.

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ACC 2013 AUC– known CAD

Table 2.3. Follow-Up Testing: New or Worsening Symptoms

Indication Text		**Exercise ECG**	**Stress RNI**	**Stress Echo**	**Stress CMR**	**Calcium Scoring**	**CCTA**	**Invasive Coronary Angiography**
57.	• Normal exercise ECG test	M	A	A	A	R	A	M
58.	• Nonobstructive CAD on coronary angiography (invasive or noninvasive) OR normal prior stress imaging study	M	A	A	A	R	R	M
59.	• Abnormal exercise ECG test	R	A	A	A	R	A	A
60.	• Abnormal prior stress imaging study	R	M	M	M	R	A	A
61.	• Obstructive CAD on CCTA study	M	A	A	A	R	R	A
62.	• Obstructive CAD on invasive coronary angiography	A	A	A	M	R	R	A
63.	• Abnormal CCTA calcium (Agatston Score >100)	A	A	A	A	R	M	A

Appropriate Use Key: A – Appropriate; M – May Be Appropriate; R – Rarely Appropriate.
A – Appropriate; CAD – coronary artery disease; CCTA – coronary computed tomography angiography; CMR – cardiac magnetic resonance; ECG – electrocardiogram; Echo – echocardiography; M – May Be Appropriate; R – Rarely Appropriate; RNI – radionuclide imaging.

Section 2.2. Post-Revascularization (PCI or CABG)

Table 2.4. Symptomatic (Ischemic Equivalent)

Indication Text		**Exercise ECG**	**Stress RNI**	**Stress Echo**	**Stress CMR**	**Calcium Scoring**	**CCTA**	**Invasive Coronary Angiography**
64.	• Evaluation of ischemic equivalent	M	A	A	A	R	M	A

A – Appropriate; CCTA – coronary computed tomography angiography; CMR – cardiac magnetic resonance; ECG – electrocardiogram; Echo – echocardiography; M – May Be Appropriate; R – Rarely Appropriate; RNI – radionuclide imaging.

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AGENCY MEDICAL DIRECTOR GROUP

Recommendation: Noninvasive Cardiac Imaging – Stress Echo

- Stress echocardiography is a covered benefit for:
  - Population:
    - Suspected CAD in symptomatic patients, or
    - Evaluation of known coronary artery disease in patients who have new or worsening symptoms, AND
  - Criteria:
    - Unable to perform ETT, or
    - Electrocardiogram (ECG) abnormality that prevents accurate interpretation of ETT

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval, pulmonary hypertension, HOCM

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AGENCY MEDICAL DIRECTOR GROUP

Recommendation: Noninvasive Cardiac Imaging - SPECT

- SPECT is a covered benefit for :
  - For patients with symptoms of myocardial ischemia (symptomatic) who are:
    - At high risk of coronary artery disease (CAD), or
    - At low to intermediate risk of CAD, and
      - Have abnormal/indeterminate exercise treadmill test (ETT), or
      - Unable to perform ETT, or
      - Electrocardiogram (ECG) abnormality that prevents accurate interpretation of ETT, and
      - Stress echocardiography is inappropriate
  - For patients with known CAD, monitoring:
    - Changes in symptoms
- SPECT is not a covered benefit for:
  - Patients with known CAD and no changes in symptoms/stable symptoms

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval, pulmonary hypertension, HOCM

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AGENCY MEDICAL DIRECTOR GROUP

Recommendation: Noninvasive Cardiac Imaging - PET

- PET is a covered benefit for:
  - Patients under the same conditions as SPECT when:
    - SPECT is not technically feasible; or
    - SPECT is inconclusive

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval, pulmonary hypertension, HOCM

29

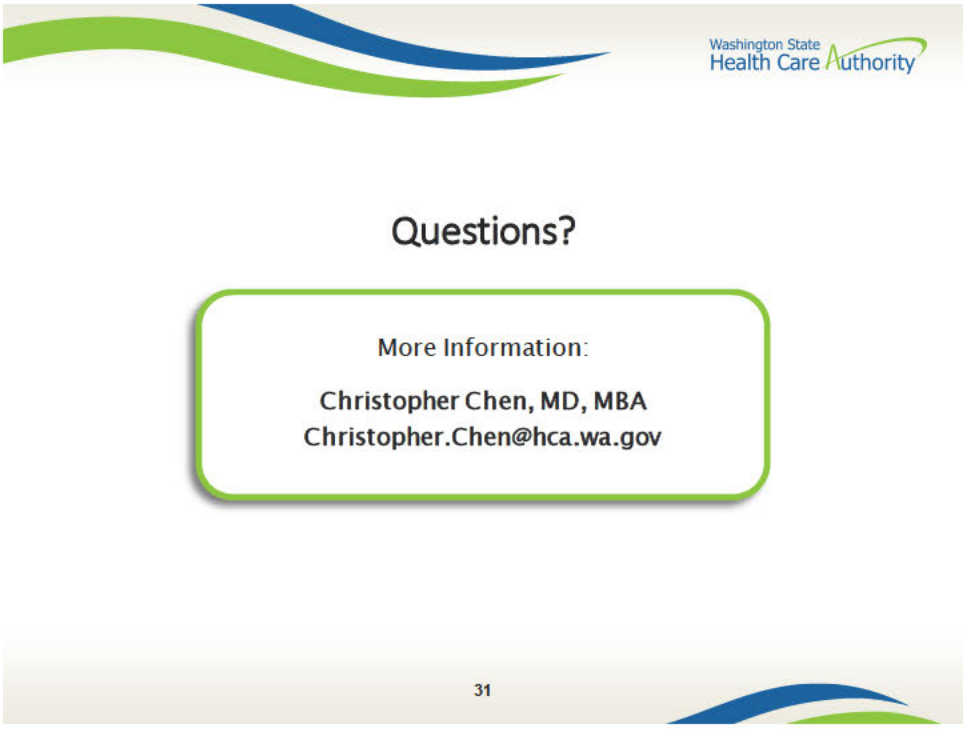
AGENCY MEDICAL DIRECTOR GROUP

Recommendation: Noninvasive Cardiac Imaging - CCTA

- CCTA is a covered benefit for:
  - Patients with low to intermediate risk of coronary artery disease;
  - Using Computed Tomography machines with 64-slice or better capability
- CCTA is not a covered benefit for:
  - Patients who are at high risk of coronary artery disease;
  - CT scanners that use lower than 64- slice technology
- CCTA with FFR is a covered benefit for:
  - Patients under the same conditions as CCTA, when further investigation of concerning stenoses identified on initial CCTA is necessary

*Out of scope: asymptomatic individuals with suspected or known CAD, post-revascularization, recent MI, Kawasaki, arrythmias, CHF, abnormal ETT/MPI/CCTA/cath, myocardial viability, valvular disease, preoperative eval, pulmonary hypertension, HOCM

30


Washington State
Health Care Authority
Questions?
More Information:
Christopher Chen, MD, MBA
Christopher.Chen@hca.wa.gov
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Washington State Health Care Authority

Order of scheduled presentations:

Non-invasive cardiac imaging for CAD

	Name
1	Susan Mayer, MD, Chair - American Society of Echocardiography Advocacy
2	Randall Thompson, MD - President, American Society of Nuclear Cardiology
3	Johnathan R. Lindner, MD – Oregon Health Sciences University

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contribute to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations. (WAC 182-55)

This Conflict of Interest form must be completed by an applicant for appointment to the State of Washington Health Technology Clinical Committee (HTCC) or appointment to any of its subcommittees or work groups.

A member of the HTCC or any of its subcommittees or work groups may not participate in discussions or deliberations of any class of drugs or any agenda item for which a conflict of interest is identified and may not vote on any such matter.

If a conflict of interest is so great as to make it difficult for any member to participate meaningfully in the work of the HTCC, that member may be asked to resign.

1 Applicant information

First name: Susan

Middle initial: A

Last name: Mayer

Phone number: [redacted]

Email: smayer9@yahoo.com

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
N/A			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topics(s):

N/A

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topics(s):

N/A

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

N/A

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying committee staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership.

Signature

Date

10/19/2021

please return form to **shtap @hca.wa.gov**, or:

Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Health Technology Clinical Committee
Conflict of Interest Disclosure

Washington State Health Care Authority

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If a conflict of interest is so great as to make it difficult for any member to participate meaningfully in the work of the HTCC, that member may be asked to resign.

1 Applicant information

First name:
Randall

Middle initial:
C

Last name:
Thompson

Phone number:
[redacted]

Email:
rthompson@saint-lukes.org

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
none			Self	Family
			Self	Family
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			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topics(s):

No. Although I have authored editorials on the importance of keeping the patient first in cardiovascular test selection.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topics(s):

None

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

[redacted] 10/14/21

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying committee staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership.

Signature [redacted]

Date 10/13/21

please return form to **shtap @hca.wa.gov**, or:

Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Comments on the HTAP WSHCA Non-Invasive Cardiac Imaging for CAD Re-Review

Ran**dall C Thompson MD, FACC, FSCCT, MASNC**

Professor of Medicine

University of Missouri – Kansas City

President

American Society of Nuclear Cardiology

1

Points of Emphasis

- Randomized control trial data indeed show no major advantages of one diagnostic test compared to another for patients with suspected CAD in the various subgroups.
- The logical conclusion is that providers should be allowed to use all the modalities in the the diagnostic toolbox based on appropriate use.
- Many, including ASNC, have long pointed out that patients are variable, the decision about which test to order is nuanced, and that local availability and expertise are very important.

2

Points of Emphasis

- The one place where the calls CCTA “dominant” was in cost-effectiveness.
- The study also point out that the data are mixed, comparators are varied, and there are important limitations across studies.
- This is indeed true. Expert center bias is also an issue.

3

EDITORIAL

Patient first versus computed tomography first strategy in testing for stable coronary artery disease: dispelling the prevailing myths and biases

Edward A. Hulten,[a,b,c] Saurabh Malhotra,[d,e] and Suman Tandon[f]

[a] Departments of Medicine, Cardiology Service, Fort Belvoir Community Hospital, Fort Belvoir, VA
[b] Walter Reed National Military Medical Center, Bethesda, MD
[c] F. Edward Hébert Medical School, Uniformed Services University of Health Sciences, Bethesda, MD
[d] Division of Cardiology, Cook County Health, John H. Stroger Hospital, Chicago, IL
[e] Division of Cardiology, Rush Medical College, Chicago, IL
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Received Dec 10, 2020; accepted Dec 11, 2020
doi:10.1007/s12350-020-02519-0

Hulten EA, J Nucl Cardiol, 2021

4

Increased Catheterization and Revascularization After CCTA

n	Design	Age, yrs	Population	Catheterization	Revascularization
282, 830	Medicare registry	73.6	Stable chest pain, outpatients, Medicare beneficiaries 66 years or older with no claims for CAD in the preceding year	22.9% after CCTA, 12.1% after UC; AOR 2.19 (2.08 to 2.32) p<0.001	PCI: 7.8% PCI after CCTA, 3.4% after UC; AOR, 2.49 (2.28 to 2.72) p<0.001 CABG: 3.7% after CCTA, 1.3% after UC; AOR, 3.00 (2.63 to 3.41) p<.001
3,266	Meta-analysis, 4 CTA vs UC ER RCT	51	Acute chest pain, Emergency dept, non-acute ECG, negative troponin, 3 of 4 exclude known CAD	8.4% after CCTA, 6.3% after UC; OR 1.36 (1.03 to 1.80) p = 0.030	4.6% after CCTA, 2.6% after UC; OR 1.81 (1.20 to 2.72) p = 0.004
14, 817	Meta-analysis, 4 CTA vs UC outpatient RCT	60	Stable chest pain, outpatients, non-acute ECG, negative troponin	12.7% after CCTA, 9.8% after UC ; AOR 1.33 (0.95–1.84) p=0.09; excluding hybrid imaging in SCOT HEART AOR 1.56 (1.38–1.78),p<0.001	7.9% after CCTA , 5.1% after UC OR 1.77 (1.14–2.75) p<0.001

Hulten EA, J Nucl Cardiol, 2021

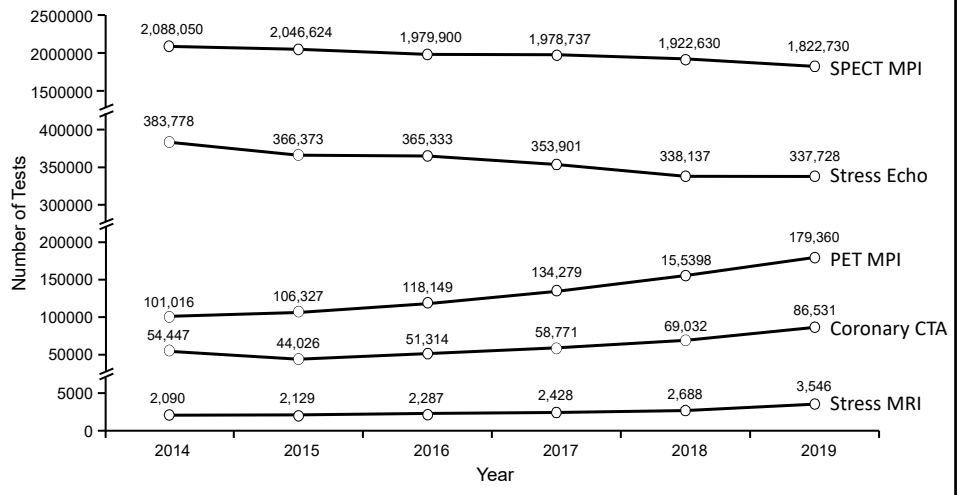
5

What is not in the review

- How to test patients with established CAD
- Individual test absolute contraindications and relative contraindications
- Combining stress testing with coronary artery calcium scoring

6

Cardiac Test Volumes 2014-2019



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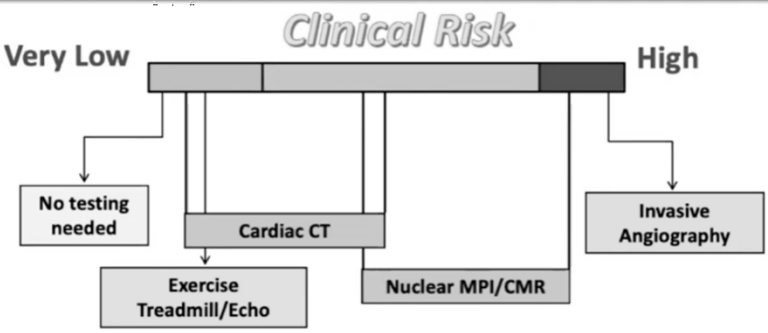
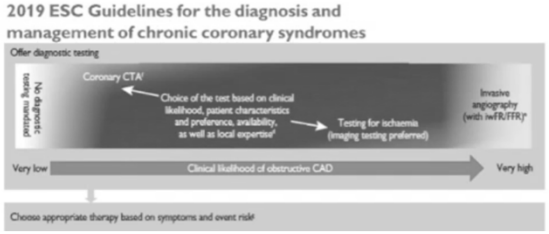
Testing options for patients with stable chest pain





2019 ESC Guidelines

8

Contraindications to CCTA

- Renal insufficiency
- Atrial fibrillation
- Fast and / or irregular heartbeat
- Very heavy coronary calcifications
- Coronary stents
- Unable to take nitroglycerin (for example on Viagra)
- Some claustrophic patients
- (Morbid obesity)

9

Contraindications for nuclear tests

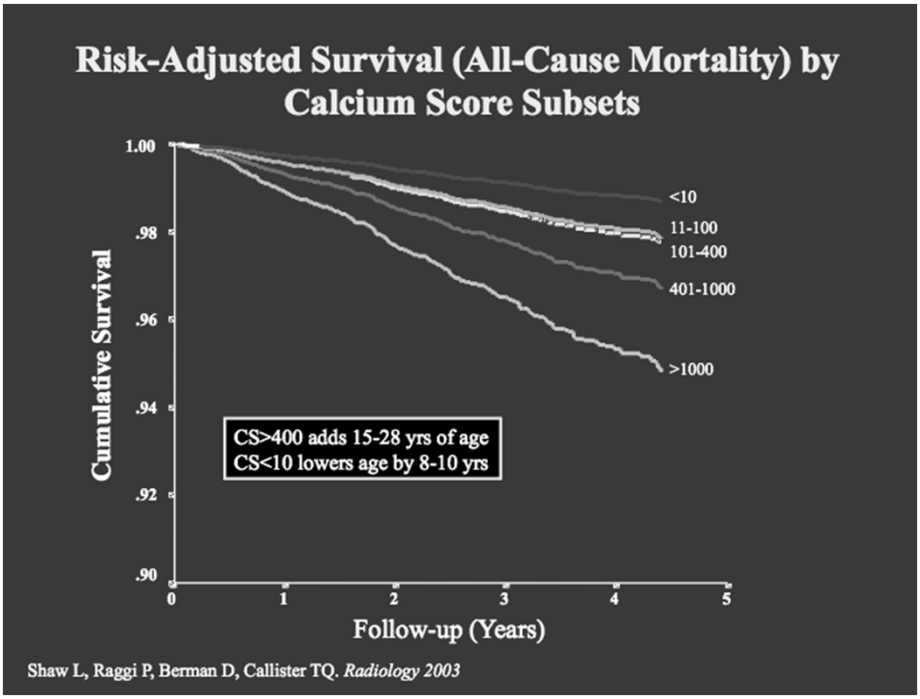
& Pharmacologic stress agents

- **Symptomatic critical aortic stenosis**
- **Acute MI / Many ACS patients**
- **Asthma / COPD, especially with recent exacerbation**

10

Combining coronary calcium scoring with stress testing.

11



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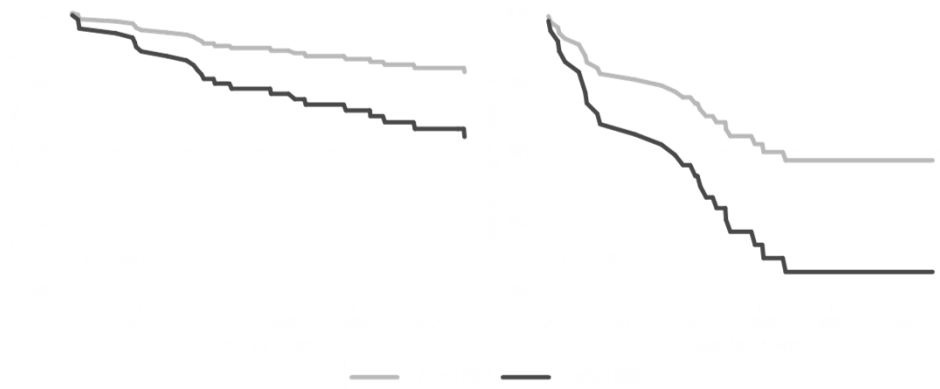
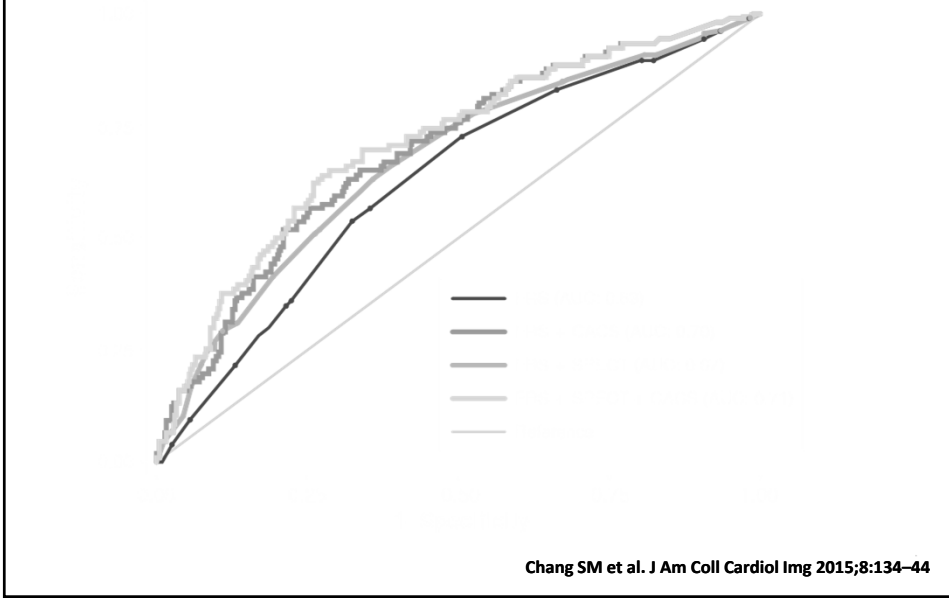
Interrelation of Coronary Calcification, Ischemia and Outcomes



Schenker et al. Circulation 2008;117:1693-1700

13

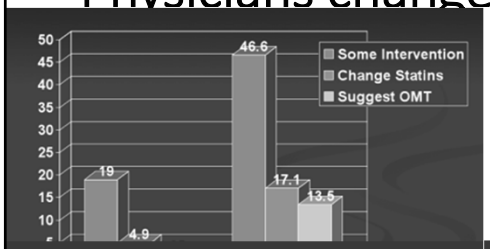
Incremental Diagnostic Value

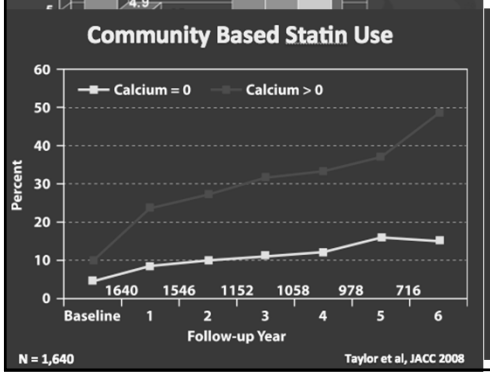


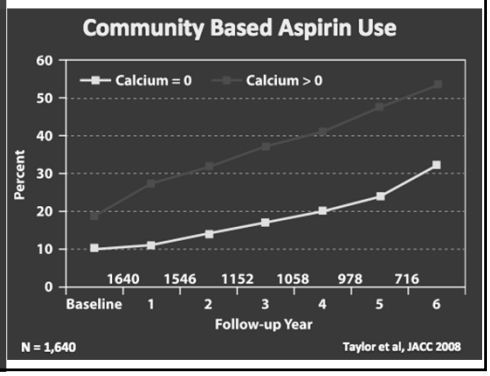
Chang SM et al. J Am Coll Cardiol Img 2015;8:134–44

14

Physicians change medical therapy







15

Summary

- The right test for the patient at the right time is a nuanced decision, patients have considerable variability, there is considerable variability in local expertise and availability, and all modalities are advancing.
- Providers with appropriate expertise, and in the context of appropriate use, should be able to utilize the best tool available for optimal patient care, and not be hindered by restrictive algorithms.

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Thank You

rthompson@saint-lukes.org

17

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contribute to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations. (WAC 182-55)

This Conflict of Interest form must be completed by an applicant for appointment to the State of Washington Health Technology Clinical Committee (HTCC) or appointment to any of its subcommittees or work groups.

A member of the HTCC or any of its subcommittees or work groups may not participate in discussions or deliberations of any class of drugs or any agenda item for which a conflict of interest is identified and may not vote on any such matter.

If a conflict of interest is so great as to make it difficult for any member to participate meaningfully in the work of the HTCC, that member may be asked to resign.

1 Applicant information

First name: Jonathan

Middle initial:

Last name: Lindner

Phone number: [redacted]

Email: lindnerj@ohsu.edu

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

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Category (A-G)	Source of income and date	Amount	Recipient	
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			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topics(s):

Yes:
Multisocietal guideline and standards documents on the multiomdality use of non-invasive imaging in CAD.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topics(s):

Yes. See above.

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

Yes. See above.

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying committee staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership.

Signature

[redacted]

Date

October 10, 2021

please return form to **shtap @hca.wa.gov**, or:

Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Noninvasive Imaging for CAD

Presentation to

Washington State Health Care Authority
Health Technology Clinical Committee

Andrea C. Skelly, PhD, MPH

November 5, 2021

Report prepared by:
Andrea C. Skelly, PhD, MPH
Erika D. Brodt
Shelby Kantner, Shay Stabler-Morris
Britt Redick, Mark Junge
Contributors:
Rita Redberg MD, MS
Bryana Banashefski, Ngoc Wasson, Reed Barton

Aggregate Analytics

1

1

Previous Reports and Rationale

2008 Report – CCTA

- 41 studies; 34 on diagnostic accuracy, 7 (6 ED, 1 OP) on clinical outcomes, decision making, only **1 RCT** (Goldstein 2007; ED setting)
- Conclusions based on models and their methods:
  - Accuracy: CCTA considered highly sensitive with moderately high specificity
  - Effectiveness:
    - Acute, low to intermediate risk patients: CCTA of comparable effectiveness vs. UC/alternative strategies and of high value (model assumes CCTA at $466)
    - OP, low to intermediate risk: CCTA rated as "unproven but with evidence of potential net benefit", reasonable or comparable value
    - CCTA may reduce ICA (modeled), would not replace other NIT
  - Safety:
    - Risk considered similar to tests using contrast
    - Radiation risks small but high enough to obviate benefit when applied to very low risk patients
    - Incidental findings are not infrequent, no evidence of improved patient outcomes balancing cost and potential harms from further testing and anxiety
- **Re-review Rationale**: new published evidence, focused on clinical outcomes, utility
  - **22 RCTs (46 publications)** (including Goldstein 2007); 14 ED, 8 OP.
  - **1 prospective cohort** evaluating CCTA-FFR (new adjunct modality)

Analytics

2

2

Previous Reports and Rationale (cont.)

2013 Report – Nuclear Stress Testing:

- 34 studies total: 26 evaluated clinical outcomes: **5 RCTs** (4 SPECT, 1 PET), 4 included in re-review (3 SPECT [Shaw 2011, Sabharwal 2007, Sharples 2007], 1 PET [Mullani]); 9 comparative cohorts (mostly retrospective, compared different protocols, stressors), 12 case series
  - Included asymptomatic patients (*excluded from this re-review*)
- Conclusions:
  - Effectiveness:
    - In low to intermediate risk: SPECT comparable or better than ETT and comparable to Echo;
    - In high risk: SPECT incremental or better than ETT and comparable to Echo;
    - In known CAD, insufficient evidence for SPECT vs. ETT and SPECT comparable to Echo.
    - All evidence for PET imaging insufficient.
  - Safety:
    - SPECT and PET appear safe, however, there is a lack of comparative data across modalities. AEs typically transient and insignificant and due to exercise or pharmacological stressors. Effective radiation dose ranged from 7-30 mSv for SPECT and 2-14 mSv for PET.
- **Re-review Rationale:** new evidence; focus on clinical outcomes and utility
  - **6 RCTs of SPECT** (including the 3 above)
  - **2 RCTs of PET** (include the 1 above)

Analytics 3

3

Continuum of Medical Testing Studies

	Objective	Terms Used	Examples
Not addressed	Test conforming to technical specifications	• Technical efficacy	• Technical quality of a radiological image
		• Analytic validity	• Chemical assay accuracy for target analyte • Concordance of a commercial genetic test with the true genotype
2021 Contextual Question	Test classifying a patient into a disease/phenotype or prognosis category	• Diagnostic accuracy efficacy • Clinical validity • Test accuracy, performance • Performance characteristics • Operating characteristics	• Sensitivity, specificity • Positive and negative likelihood ratios • Positive, negative predictive value • Test yield • Receiver operating characteristic curve
2021 Focus	**Test directing management and improving patient outcomes**	**• Diagnostic thinking efficacy • Therapeutic efficacy • Patient outcome efficacy • Clinical utility**	**• Impact on mortality or morbidity • Impact on clinician judgment • Impact on choice of management**
	Benefiting society	**• Societal efficacy**	**• Incremental cost-effectiveness**

Matchar DB. Introduction to the *Methods Guide for Medical Test Reviews*. In: Methods guide for medical test reviews. Available at www.effectivehealthcare.ahrq.gov/medtestsguide.cfm. ι Fryback DG, Thornbury JR. Med Decis Making 1991 Apr-Jun;11(2):88-94. PMID: 1907710.

4

Background

Coronary artery disease (CAD); Ischemic Heart Disease (IHD)

- 2019: Leading cause of death in U.S.: 291.93 deaths per 100,000 and in WA: 241.71 deaths per 100,000
- Annually, ~605,000 Americans have new MI and ~200,000 have recurrent MI. As of 2016, health care spending related to CAD was over $89 billion (54% public payer, 42% private payer, 4% out of pocket)
- **CAD/IHD**: chronic, spans decades; typically cycles through clinically defined phases: asymptomatic, stable angina, accelerating angina and acute coronary syndrome; progression may not be linear (European Society of Cardiology Guideline 2019, Fihn 2012 ACC Guideline)
- **Atherosclerosis**: Plaque builds on artery walls, may obstruct the vessel preventing cardiac muscle from receiving blood, oxygen; disruption of stable plaque may cause bleeding/thrombus formation, increase obstruction and result in unstable angina and MI.
- **Symptoms** do **not** always correlate with lesion presence or severity. Ischemia may be present without observable obstruction.

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5

Background

Traditional clinical classification of suspected anginal symptoms

Typical angina	Meets the following three characteristics: (i) Constricting discomfort in the front of the chest or in the neck, jaw, shoulder, or arm; (ii) Precipitated by physical exertion; (iii) Relieved by rest or nitrates within 5 min.
Atypical angina	Meets 2 of the above
Non-anginal chest pain	Meets 1 or none of the above

- Patient history used to categorize stable or unstable angina
- Stable angina
  - Chest discomfort 1) presenting in a predictable pattern, 2) brought on by physical or mental stress 3) subsides with rest or angina medications (King 2007 guideline)
  - Associated with stenosis, without plaque disruption or plaque-associated thrombosis

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6

6

Canadian Cardiovascular Society (CCS) Classification of Angina

Class	Clinical Findings	Angina may be induced
Class I	No limitations of ordinary activity	• With strenuous, rapid, or prolonged exertion • Ordinary physical activity, such as walking or climbing stairs, does not cause angina.
Class II	Some limitations of ordinary activity	• Rapidly walking or climbing stairs; walking uphill; • Walking >2 blocks on level surface or > 1 flight of stairs at normal pace under normal conditions • Walking or climbing stairs after meals, in cold, in wind, within the first few hours after awakening
Class III	Significant (marked) limitations of normal physical activity	• Walking 1-2 level blocks; and • Climbing 1 flight of stairs under normal conditions and at normal pace
Class IV	Inability to carry on any normal physical activity without discomfort.	• Angina may occur while at rest

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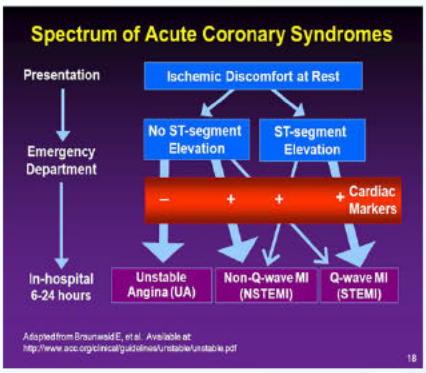
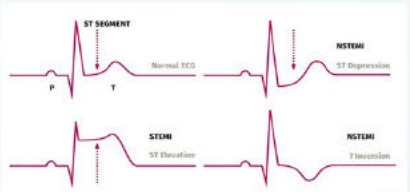
Acute Coronary Syndromes (ACS): Spectrum of conditions compatible with acute myocardial ischemia and/or infarction due to abrupt reduction in coronary flow





- **Unstable angina (UA)** = new onset (w/in 2 months) of ≥ CCS III, increasing (frequency, intensity, duration) or at rest, usually prolonged (>20 min)
  - UA subdivisions based on short-term risk of death, nonfatal MI
  - Low short-term risk: normal, unchanged ECG, normal cardiac markers, consider comparable to stable angina patients
  - Frequently associated with plaque disruption, nonocclusive plaque-associated thrombus, may have associated thromboemboli; cardiac biomarkers are negative
- **NSTEMI: Non-ST elevation MI**
- **STEMI: ST-elevation MI (not included in HTA)**

8

8

Clinical outcomes, the value of testing

- Value of a medical test relates to its ability identify persons for whom there are appropriate and effective treatments
- Outcomes are a function of test results ***in combination with*** the treatments received or other decisions made on the basis of test results
- Value of imaging for assisting with decisions to initiate, discontinue, continue or change therapy and impact on clinical outcomes also indirect
- Clinicians and clinical guidelines consider the imaging modalities in the HTA to be superior to ETT; UC generally includes imaging
- Lack of consensus regarding superiority/inferiority of noninvasive imaging tests; choice influenced by many factors

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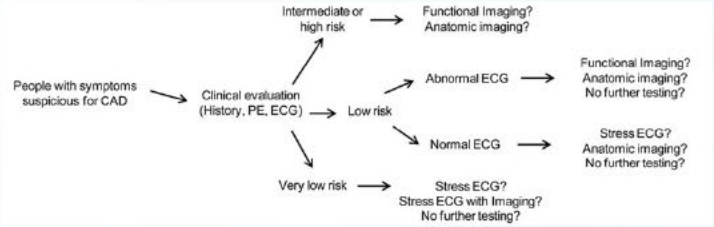
9

Overview: Diagnosis of CAD

Diagnosis

Noninvasive testing (including stress /functional testing)

Invasive coronary angiography (ICA)



- ACC Guideline: "low to intermediate" risk, 10% to 90% risk of event w/in 5 years.
- Low pretest risk: balance of FN with need for diagnosis; events rare.
- Patients at high risk for STEMI or death likely go directly to ICA and urgent revascularization is considered; they are not included in this HTA.

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Figure from Skelly AC, Hashimoto R, Buckley DI, et. al. Noninvasive Testing for Coronary Artery Disease. Comparative Effectiveness Review No. 171. AHRQ Publication No. 16-EHC011-EF. 2016

10

10

Overview: Initial Treatment

Treatment – optimized base on patient presentation

Medical therapy (optimal MT, guideline directed MT)

- Lifestyle, education, pharmacological
- All CAD patients

Revascularization (in addition to GDMT)

- PCI, CABG

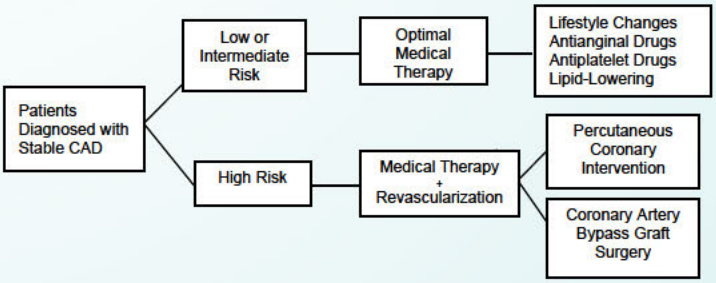


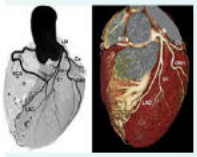
Figure from Skelly AC, Hashimoto R, Buckley DI, et. al. Noninvasive Testing for Coronary Artery Disease. Comparative Effectiveness Review No. 171. AHRQ Publication No. 16-EHC011-EF. 2016

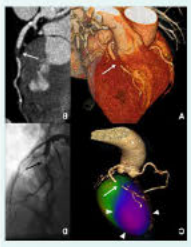
11

11

Background: CCTA

- Noninvasive, x-rays and iodinated contrast used to evaluate coronary artery anatomy and visually estimate obstruction
- **Potential advantages**: visualizes obstruction; moderate to larger hospitals have CT; may identify causes of chest pain unrelated to the heart
- **Potential disadvantages**: involves radiation; requires specialized equipment and interpretation expertise; does not provide functional information; will not confirm ischemia as a standalone test; images may be uninterpretable if substantial coronary artery calcium, rapid heart rate and presence of stents
- Lack of consensus on the effectiveness of CCTA vs. functional testing
- New adjuncts to evaluate function: FFR derived from CT data (FFRct); use of pharmacologic stress referred to as CT perfusion (CTP)
- FFRct: 1 FDA approved method; data sent to single vendor; concerns related to delayed evaluation for decision making





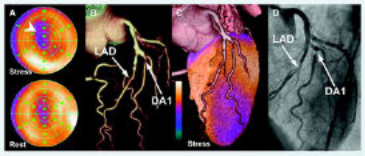
Images: Circulation. Coronary Artery Computed Tomography Scanning, Volume: 129, Issue: 12, , Pages: 1341-1345

12

12

Background: Nuclear Stress Testing (a.k.a. Myocardial Perfusion Imaging)

- Utilizes small amounts of radioactive materials (i.e., radiotracers) to evaluate physiological function
- Imaging performed using either SPECT (more common) or PET technology
  - **SPECT**: Thallium-201 (201Tl), technetium-99m (99mTc)-sestamibi, and 99mTc-tetrofosmin
  - **PET**: Rubidium (Rb)-82 chloride (used by both trials included in this re-review), N-13 ammonia (assess myocardial blood flow); ^{18}fluorodeoxy-D-glucose (^{18}FDG) (assess myocardial viability)
- **Potential advantages**: Can evaluate perfusion and wall motion, prior MI; May be preferred for patients with left bundle branch block and is useful for patients with poor echocardiography windows; PET may be preferred for assessment of suspected CAD in women and patients who are obese
- **Potential disadvantages**: Exposure to radiation from radionuclides; claustrophobia; PET scans are limited to pharmacologic stress; potential for allergic reaction; substantial expertise required for interpretation; equipment availability (PET in particular)



(A) Perfusion polar maps of SPECT-MPI at stress and rest show largely reversible anteroapical perfusion defect (arrowhead). Oliver Gaemperli et al. J Nucl Med 2007;48:696-703

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13

13

Background: Radiation safety - general

- Cardiovascular-related tests and procedures comprise about 40% of all medical radiation exposure
- Increased concerns about cumulative radiation exposure from all tests across a lifetime
- Large registries and international studies have shown wide variation in average radiation dose per procedure
- Table 1 provides overview of radiation exposure
- **Radiation exposure**: a measure of the quantity of ionization produced in air by photon irradiation
- **Radiation dose ("absorbed radiation dose")**: the amount of radiation energy deposited in the human body as a result of exposure to ionization

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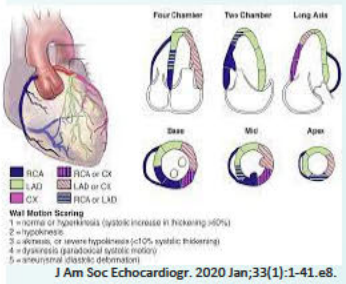
14

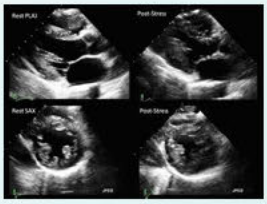
14

Background: Stress Echocardiography

- Established CAD diagnostic method
- Ultrasound provides a functional assessment of impact of obstruction or ischemia on cardiac function and anatomy
  - Stress induced by either exercise or a pharmaceutical agent (typically, Dobutamine)
- **Potential advantages**: functional information via wall motion analysis, diastolic function, can evaluate integrity of cardiac structures,, prior infarct; widely available; portable; inexpensive (vs. other imaging modalities for CAD); does not involve ionizing radiation; established protocols
- **Potential disadvantages**: may be difficult to perform/interpret in obese patients or those with pulmonary disease; operator dependent and requires substantial expertise for comprehensive, accurate interpretation; does not directly visualize coronary arteries



J Am Soc Echocardiogr. 2020 Jan;33(1):1-41.e8.



Kosaraju,STATPEARLS https://www.statpearls.com/ArticleLibrary/viewarticle/128

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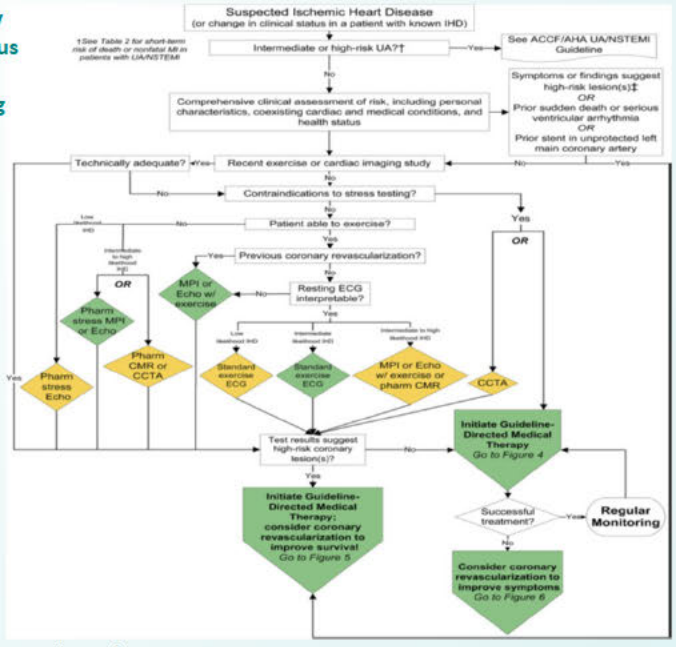
There is controversy and lack of consensus regarding optimal noninvasive imaging approaches

ACCF 2012 Guideline – Diagnosis Suspected IHD



Fihn et. al., JACC 2012;60:e44 –164

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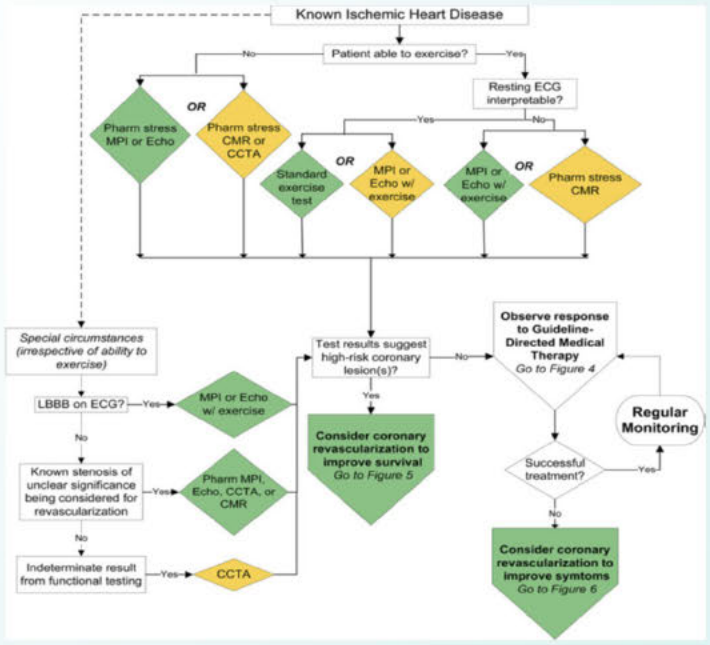
ACCF 2012 Guideline – Stable IHD



Fihn et. al., JACC 2012;60:e44 –164

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ACCF: Appropriate Use – Stable IHD

Table 1.1. Symptomatic

Refer to pages 16 and 17 for relevant definitions, in particular Table A and text for age, sex, symptom presentation, and risk factors relevant to each pre-test probability category

	Indication Text	Exercise ECG	Stress RNI	Stress Echo	Stress CMR	Calcium Scoring	CCTA	Invasive Coronary Angiography
1.	• Low pre-test probability of CAD • ECG interpretable AND able to exercise	A	R	M	R	R	R	R
2.	• Low pre-test probability of CAD • ECG uninterpretable OR unable to exercise		A	A	M	R	M	R
3.	• Intermediate pre-test probability of CAD • ECG interpretable AND able to exercise	A	A	A	M	R	M	R
4.	• Intermediate pre-test probability of CAD • ECG uninterpretable OR unable to exercise		A	A	A	R	A	M
5.	• High pre-test probability of CAD ECG interpretable AND able to exercise	M	A	A	A	R	M	A
6.	• High pre-test probability of CAD • ECG uninterpretable OR unable to exercise		A	A	A	R	M	A

Appropriate Use Key: A – Appropriate; M – May Be Appropriate; R – Rarely Appropriate.
A – Appropriate; CAD – coronary artery disease; CCTA – coronary computed tomography angiography; CMR – cardiac magnetic resonance; ECG – electrocardiogram; Echo – echocardiography; M – May Be Appropriate; R – Rarely Appropriate; RNI – radionuclide imaging.

Wolk, et. al., J Am Coll Cardiol 2014;63:380–406.

There is controversy and lack of consensus regarding optimal noninvasive imaging approaches particularly in low to intermediate pretest risk patients

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Questions and Scope

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Contextual Questions

In patients with **known or suspected CAD who are symptomatic**:

What is the diagnostic accuracy of the tests compared with ICA? And is there evidence of differential test accuracy for specific subpopulations?

Specifically:

1. Sensitivity and specificity and prognostic value (positive and negative predictive values)
2. Inter- and intra-rater reliability (reproducibility)

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Key Questions

FOCUS: clinical outcomes, decision making, harms, HTE, CE

1. What is the comparative effectiveness of the tests on improved clinical outcomes (e.g., MI, mortality)?
2. What is the comparative effectiveness of the tests on clinical decision-making including additional testing and treatments?
3. What is the comparative evidence regarding harms or adverse events which may result directly from testing or additional, downstream testing?
4. Does effectiveness (in terms of clinical outcomes) or safety differ in special populations (e.g., women, those with comorbidities, the elderly)?
5. What is the cost-effectiveness of noninvasive cardiac anatomic or functional imaging modalities for clinical outcomes?

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PICO Scope: Inclusion Criteria

- **Population**:
  - Symptomatic adults with suspected CAD, known/established CAD including those who have had prior MI and/or revascularization; acute chest pain, suspected ACS (UA or NSTEMI)
- **Interventions:**
  - Coronary CT Angiography (including FFR), CT pharmacologic stress, (≥64 slice CT)
  - Stress nuclear imaging (including PET, SPECT)
  - Stress echocardiography
- **Comparators:**
  - No testing
  - Usual care
  - Comparison of the above interventions with each other
  - Invasive coronary angiography
- **Primary Outcomes (SOE):**
  - Clinical: MI, cardiac death, all-cause mortality
  - Decision making: Referral for treatment, referral for additional testing
  - Safety: Harms of testing, risks and consequences of testing, radiation, incidental findings
  - Cost-effectiveness outcomes: QALY, ICER

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PICO Scope: Inclusion Criteria

- **Timing:**
  - Emergent or non-emergent
  - Any point in the diagnostic workup
- **Setting(s):**
  - Emergency department or similar
  - Non-emergent settings
- **Study Design:**
  - KQ 1, 2, 3, 4: Focus will start with RCT evidence; in the absence of RCTs, high quality comparative observational studies that control for potential confounding will be considered
  - KQ 5: Full formal economic analyses
  - Studies published in English after 2000 (except for stress echocardiography)

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Methods

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Individual Studies: Risk of Bias

Criteria
• Random sequence generation (RCT)
• Statement of allocation concealment (RCT)
• Intent-to-treat analysis (RCT)
• Blind, independent assessment of test
• Blind or independent assessment, subjective outcome(s)
• Prespecified threshold for definition of a positive test
• Attrition (≤ 20% overall, <10% between arms)
• Comparable f/u time or accounting for time at risk
• Controlling for possible confounding
• Full reporting of specified outcomes

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Strength of Evidence (SOE) Criteria – Appendices

Overall *body of evidence* for primary outcomes:

- **Risk of bias (one criterion)**: the extent to which the included studies protect against bias in majority of studies
- **Consistency:** degree to which estimates are similar in terms of range and variability.
- **Directness:** evidence directly related to patient health outcomes.
- **Precision**: level of certainty surrounding the effect estimates.
- **Publication/reporting bias:** selective reporting or publishing.

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Systematic Review Process

Studies meeting eligibility criteria
Efficacy: RCTs (effectiveness)
Harms: RCTs, observational studies
Economic studies

Risk of Bias Appraisal (Study)
Good, Fair, or Poor
Synthesis/analysis

Overall Strength of Evidence Determination (GRADE/AHRQ)

Strength of Evidence Ratings	
High	Very confident that effect is true.
Moderate	Moderately confident.
Low	Limited confidence.
Insufficient	No evidence or no confidence in effect.

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Organization of results

Contextual Question results

Key question 1-4 results by noninvasive test*

KQ 1. Effectiveness-impact on MI and mortality

KQ 2. Impact on clinical decision-making

- Referral for ICA and additional testing
- Referral for treatment (revascularization, other)
- Hospitalization

KQ 3. Safety

KQ 4. Differential effectiveness or safety

KQ 5. Cost-effectiveness (across tests)

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*Evidence on efficacy for FFRct was insufficient and will not be presented.
No prospective comparative studies of CT perfusion were identified

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Contextual question: Overview of Test accuracy vs. ICA

	CCTA	SPECT	PET	Stress Echo
Sensitivity	96% to 100% (93.4% to 100%)	81% to 85% (76% to 87%)	82% to 91% (82% to 91%)	76% to 87% (64% to 90%)
Specificity	79% to 89% (72% to 92%)	77% to 85% (70% to 92%)	86% to 88% (82% to 91%)	72% to 80% (72% to 96%)
PPV	84% to 93% (47% to 93%)	79% to 88% (32% to 95%)	87% to 96% (78% to 96%)	85% to 93% (72% to 98%)
NPV	97% to 99% (89% to 100%)	65% to 95% (47% to 97%)	53% to 90% (53% to 94%)	62% to 97% (36% to 97%)
LR+	4.57 to 9.2 (3.43 to 12.50)	3.56 to 5.13 (2.88 to 10.48)	5.57 to 6.50 (4.97 to 8.89)	3.08 to 3.8 (3.08 to 18.67)
LR-	0 to 0.05 (0 to 2.64)	0.18 to 0.24 (0.18 to 2.33)	0.10 to 0.21 (0.10 to 0.21)	0.18 to 23.0 (0.13 to 2.95)
CAD prevalence (all sources)	24.2% to 75.5%	14.1% to 86%	36.5% to 80%	35.1% to 90.8%

ICA is an anatomic test, so accuracy for anatomic tests such as CCTA may differ from functional tests such as stress nuclear imaging or stress echocardiography.

No studies of differential accuracy by subgroups identified.

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Contextual question: Test accuracy vs. ICA

	FFRct	CT perfusion
Sensitivity	84% to 91%	54% to 66%
Specificity	55% to 84%	98% to 100%
PPV	58% to 100%	96% to 100%
NPV	0% to 90%	66% to 100%
LR+	2.02 to 3.70	33.00 to 54.00
LR-	0.16 to 0.23	0.45 to 0.47
CAD prevalence ranges	32% to 100%	NR

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Contextual question: Reliability

CCTA

- Inter-rater: CCTA moderate to almost perfect (k=0.58 to 0.94), CTP substantial to almost perfect (k=0.72 to 0.86)
- Intra-rater: CCTA substantial to almost perfect (k=0.72 to 0.96), FFRct: fair to almost perfect (k=0.40 to 0.94)

SPECT and PET intra- and inter-rater

- Almost perfect for SPECT (k=0.96, k=0.91 to 0.95) and PET (k=0.94, k=0.82)

Stress echocardiography

- Inter-rater: moderate to almost perfect (k=0.56 to 0.87)
- Intra-rater: almost perfect agreement (k=0.81 to 0.90)

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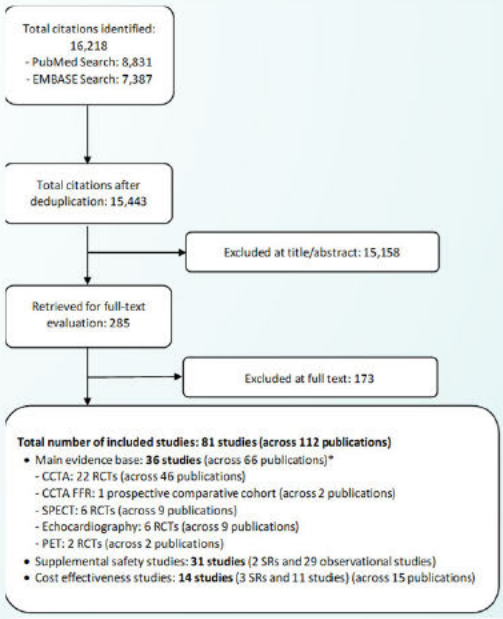
Results of literature search



CCTA = coronary computed tomography angiography; FFR = fractional flow reserve; PET = positron emission tomography; RCT = randomized control trial; SPECT = single photon emission tomography; SR = systematic review
* One trial (CECaT trial) provided data for both SPECT and Stress Echocardiogram.

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Key Question 1 – 4
Results
CCTA vs. Functional testing

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Patient characteristics: CCTA vs. functional testing

Patients with suspected ACS (14 RCTs; N=3,818)	Stable OP with suspected CAD 6 RCTs (N=16,182)
Patients' pre-test risk for CAD - Very low-to-low: 1 trial - Low: 1 trial - Low-to-intermediate: 8 trials - Intermediate: 2 trials - Mixed: 1 trial - Not reported: 1 trial	**Patients' pre-test risk for CAD** - Low-to-intermediate: 1 trial - Intermediate: 1 trial - Intermediate-to-high: 1 trial - Mixed: 2 trials - Not reported: 1 trial
Mean age 49-64 years, **female** 39% to 63%, **non-white race** 33%-95% (7 trials)	**Mean age** 57-61 years, **female** 44% to 53%, **non-white race** 22%-29% (3 trials)
- 8 trials excluded patients with known CAD - 2 trials, 14% and 15% of patients had known CAD	- 5 trials excluded patients with known CAD - 4 trials excluded patients with prior revascularizations
Cardiac risk factors: dyspnea (2%-49%, 2 trials), hypertension (17%-72%, 13 trials), hyperlipidemia (25%-52%, 11 trials), diabetes (6%-32%, 12 trials), smoking hx (14%-49%, 13 RCTs)	**Cardiac risk factors**: dyspnea (10%-15%, 2 trials), hyperlipidemia (57%-68%, 3 trials)

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Study & test characteristics: CCTA vs. functional testing

Patients with suspected ACS (14 RCTs; N=3,818)	Stable OP with suspected CAD 6 RCTs (N=16,182)
Emergency Department: 10 trials **Inpatient setting**: 3 trials **Outpatient setting**: 1 trial	**Outpatient setting**: 6 trials
Specific functional tests - Any functional testing: 6 trials (N=3,818) - SPECT: 4 trials (N=1,944) - Stress echocardiography: 3 trials (N=1,014) - Exercise ECG: 1 trial (N=562)	**Specific functional tests** - Any functional testing: 1 trial (N=10,003) - SPECT: 3 trials (N=1,533) - Exercise ECG: 2 trials (N=4,646)
Use of iodinated contrast: 9 RCTs **CACS as part of CCTA protocol**: 7 RCTs	**Use of iodinated contrast**: 2 RCTs **CACS as part of CCTA protocol**: 2 RCTs
Industry funding (2 RCT), government funding (4 RCTs), non-profit foundations (4 RCTs), no funding (1 RCTs),funding information NR (3 RCTs)	Industry funding (1 RCT), government funding (4 trials), International organization (1 RCT)

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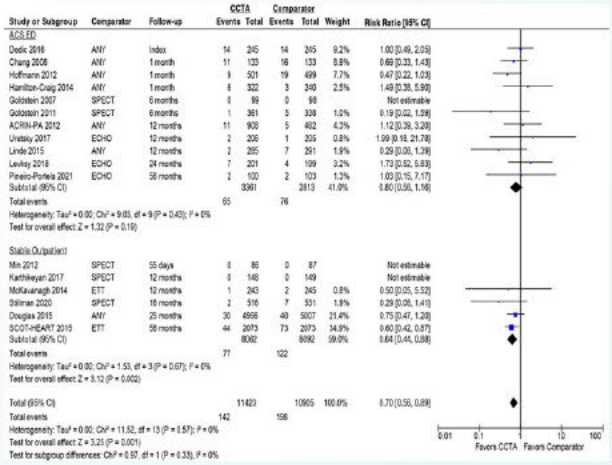
KQ 1 MI: CCTA vs. functional testing, all populations



3 trials (N=667), no MI in either testing arm

Pooled results

All studies
(14 RCTs, N=21,661)
1.2 vs. 1.8 per 100
RR 0.70 (0.56 to 0.89)
RD 0.4, (0.1 to 0.8 per 100)

Exclude SCOT-HEART
(13 RCTs, N= 17,515)
1.0 vs. 1.4 per 100
RR 0.75, (0.57 to 0.99)
RD 0.3, (0 to 0.5 per 100)

CCTA vs. Imaging only
(11 RCTS, N= 16, 465)
RR 0.74 (0.55 to 0.98)

No clear difference in MI (SOE MODERATE)

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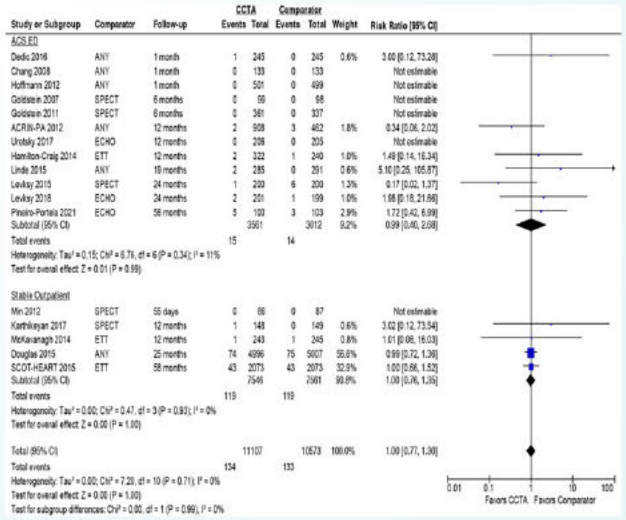
KQ 1 All-cause mortality: CCTA vs. functional testing, all populations



6 trials (N=2746), no events in either arm

Pooled results

Primary: 11 RCTs, N=18,935)
1.2 vs. 1.3 per 100
RR 0.99 (0.40 to 2.68)
No RD, NS

Exclude SCOT-HEART
1.0 vs. 1.1 per 100
RR 1.0, (0.69 to 1.0)

- **Across populations: No difference in all-cause mortality (SOE Moderate)**
- NS difference in either population

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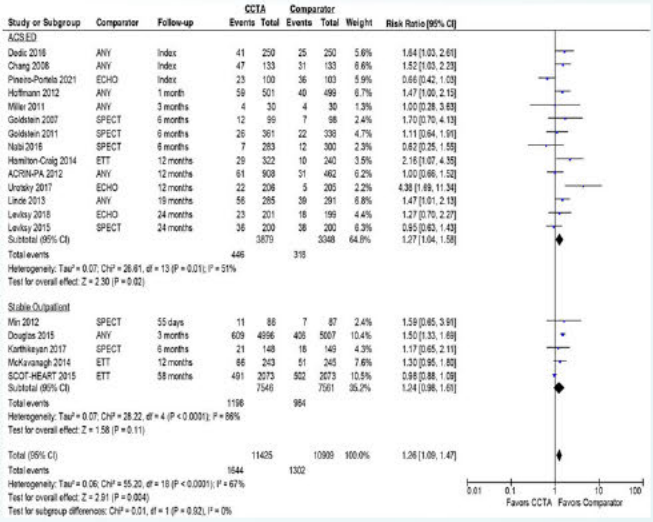
KQ 2 ICA referral: CCTA vs. functional testing, all populations



Pooled results
19 RCTS (N= 22,335)

Primary:
14.4 vs. 12.0 per 100
RR 1.25 (1.09 to 1.47)
I^2=67%
RD 2.7, (1 to 4 per 100)

Exclude SCOT-HEART
12.3 vs. 9.1 per 100
RR 1.31, (1.12 to 1.51)
I^2=45%
RD 3, (1.3 to 4.7 per 100)

ICA referral more common with CCTA vs. other tests (SOE Moderate)

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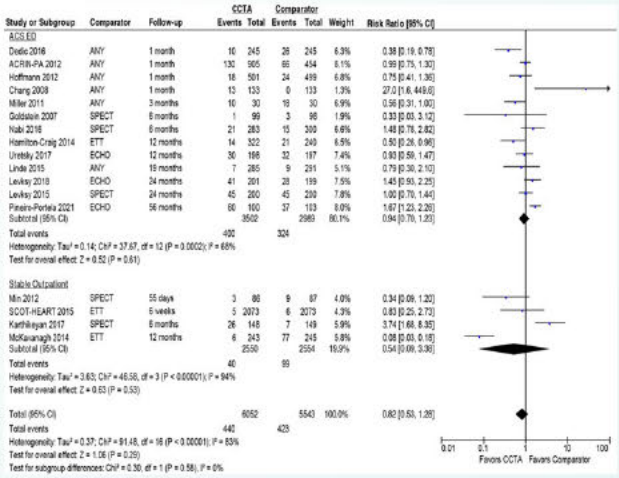
KQ 2: Additional NIT, CCTA vs. functional testing, all populations



Pooled results
17 RCTS (N=11,595)

Primary:
7.2 vs. 7.6 per 100
RR 0.82 (0.53 to 1.28)
I^2=83%

Exclusion of outliers:
(15 RCTs, N=10,841)
RR 0.92 (0.68 to 1.25)
I^2=69.3%

- **NS difference between tests: SOE Low**
- **Unexplained heterogeneity particularly in stable OP**

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KQ 2 NIT–imaging and radiation: CCTA vs. functional testing

Stable OP: appears to be mostly stress imaging involving radiation

Suspected ACS

No difference on use of **any additional** NIT at any time frame after index test by testing arm

- < 6 months after index test: 7 RCTs, RR 0.82, (0.51 to 1.41)
- ≥12 months: 7 RCTs, RR 1.05, 95% CI 0.74 to 1.39

No difference between CTTA and functional tests in referral for **stress imaging** (11 RCTs, pooled RR 0.97, 95%CI 0.73 to 1.19, I^2=38%) across time frames.

Additional testing involving radiation was inconsistently described; no SOE done

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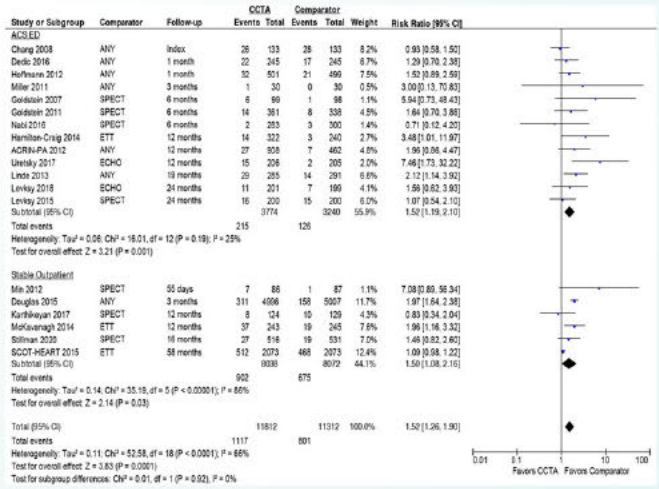
KQ 2 Revascularization: CCTA vs. functional testing



Pooled results
19 RCTS (N=23,124)

Primary:
9.5 vs. 7.1 per 100
RR 1.52 (1.26 to 1.90)
I^2=66%
RD 2.4, (1.4 to 3.3 per 100)

Exclude SCOT-HEART:
(18 RCTs, N=18,978)
6.2 vs. 3.6 per 100
RR 1.63, (1.33 to 1.98),
I^2=31%
RD 2.4, (1.4 to 3.5 per 100)

- CCTA was consistently associated with more frequent revascularization (SOE Moderate)

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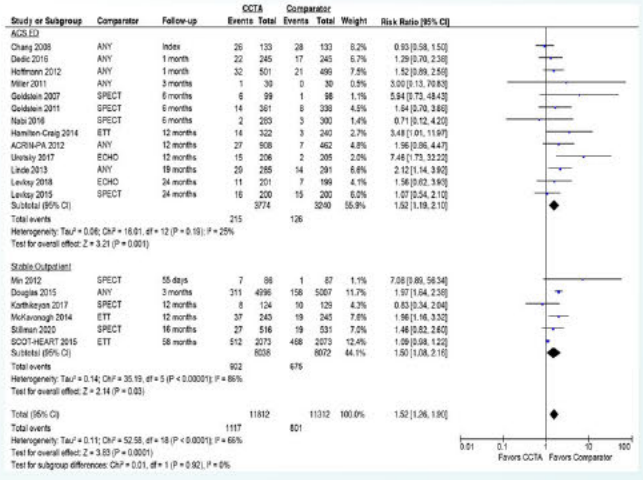
KQ 2 PCI: CCTA vs. functional testing



Pooled results
12 RCTS (N=18,960)

Primary:
8.2 vs. 6.0 per 100
RR 1.63 (1.3 to 3.6)
I^2=74%
RD 2.4, (1.4 to 3.3 per 100)

Exclude SCOT-HEART:
(11 RCTs, N=14,814)
5.1 vs. 2.6 per 100
RR 1.89, (1.38 to 2.43),
I^2=36%
RD 2.6, (1.3 to 4 per 100)

- CCTA was consistently associated with more frequent PCI (SOE Moderate)

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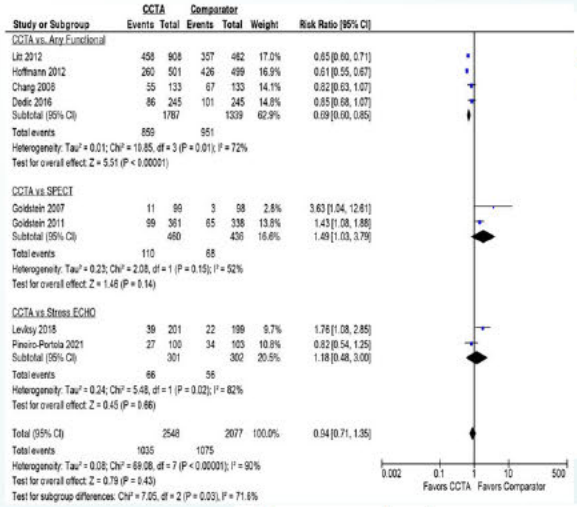
KQ 2 Hospitalization: CCTA vs. functional testing
Suspected ACS – at INDEX TEST



Substantial heterogeneity
Results differ by comparator

- CCTA vs. "any" functional testing: less hospitalization with CCTA
- CCTA vs. SPECT: difference unclear, tends to favor SPECT
- CCTA vs. stress echo: mixed results, largest RCT tends to favor stress echo

Firm conclusions cannot be drawn

SOE INSUFFICIENT

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KQ 2 Hospitalization: CCTA vs. functional testing

Hospitalization, ED revisit following index in ED patients with suspected ACS:
No difference at any time following index visit

Outcome	Follow-up	Studies	Downgrades	Conclusion Effect Estimate (95% CI)	Quality (SOE)
Hospitalization ***After index***	1 to 6.5 months	9 RCTs	ROB Yes (-1)	3.0 vs. 3 9 per 100 patients, RR 0.76, 95% CI 0.49 to 1.1, I^2=18%	⊕⊕⊕⊕ HIGH
	≥12 months	6 RCTs	ROB Yes (-1)	14 9 vs. 17.4 per 100 patients, RR 0.90, 95% CI 0.77 to 1.03, I^2=0%	⊕⊕⊕⊕ HIGH
Subsequent ED visits after index visit	1 to 6.5 months	7 RCTs	ROB Yes (-1)	5.9 vs. 6.7 per 100 patients RR 0.84, 95% CI 0.66 to 1.06, I^2=0%	⊕⊕⊕⊕ HIGH
	≥12 months	5 RCTs	ROB Yes (-1)	30 5 per 30.8 per 100 patients, RR 1.06, 95% CI 0 93 to 1.56, I^2=16%	⊕⊕⊕⊕ HIGH

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KQ 2 Hospitalization: CCTA vs. functional testing

Hospitalization (any): Stable OP patients with suspected CAD

Outcome	Time	Studies	Downgrades	Conclusion Effect Estimate (95% CI)	Quality (SOE)
Hospitalization ***Stable Outpatients***	Any	4 RCTs (N=14,810)	ROB (-1) Inconsistency (-1)	**CCTA vs. functional testing** **Risk:** 4.3 vs. 4.5 per 100 patients, **RR** 1.00, 95% CI 0.29 to 1.75, I^2=77% **Conclusions: No difference in hospitalization**	⊕⊕⊕◯ MODERATE

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KQ 3 Safety

CCTA vs. functional testing

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KQ 3 Safety: CCTA vs. functional test

Major test-related AEs and hospital admission for test-related complications was rare, there are no differences between testing arms; some RCTS may have been underpowered

SOE LOW

Outcome	Follow-up	Studies	Downgrade	Conclusion Effect Estimate (95% CI)	Quality (SOE)
Any major test-related AE	Index test up to 24 hours	**3 RCTs (N= 10,270)** Stable OP 1 RCT (N= 9470) Suspected ACS (N=800)	ROB (-1) Imprecision (-1)	**CCTA vs. Functional testing** 0% vs. 0%	⊕⊕◯◯ LOW
Hospital admission for test-related complication	Index test up to 24 hours	**1 RCT (N=9470) Stable outpatients**	Unknown consistency Imprecision(-1)	**CCTA vs. any functional test** 0% vs. 0.1% (stress nuclear)	⊕⊕◯◯ LOW

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KQ 3 Safety

Contrast-related AEs were rare.

Some RCTS may have been underpowered

Outcome	Follow-up	Studies	Downgrade	Conclusion Effect Estimate (95% CI)	Quality (SOE)
Extravasation CCTA arms only	Index test to 24 hours	**Stable OP** 2 RCTs(N=6411) **Suspected ACS** 1 RCT (N= 500)	ROB (-1) Imprecision (-1)	**Stable OP:** 0.3% to 0.4% **Suspected ACS:** 2%	⊕⊕◯◯ LOW
Transient creatinine ↑		**Suspected ACS** 2 RCTs (N=1500)	ROB (-1) Imprecision (-1)	**CCTA** 0.2% to 1% **Functional test:** 0% to 0.4%	
Mild, allergic reaction, skin rash, reaction, pruritis CCTA arms only		**Stable OP** 2 RCTs (N=6411) **Suspected ACS** 3 RCTs (N=596)	Imprecision (-2)	**Stable OP:** 0 5% (35/6411) **Suspected ACS:** 1.2% (7/569)	
Nephropathy		1 RCT (N= 266)	ROB (-1) Unknown consistency Imprecision (-1)	No cases of occurred	⊕◯◯◯ **INSUFFICIENT**

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KQ 3 Safety

Stress test related symptoms were generally rare; most are expected responses to pharmacologic stress and not due to ischemia

Outcome	Follow-up	Studies	Downgrade	Conclusion Effect Estimate (95% CI)	Quality (SOE)
Chest pain (CP), shortness of breath (SOB), or palpitations Stress-Related symptoms (unspecified) and dipyridamole, adenosine-related events	Index test up to 24 hours	Suspected ACS 2 RCTS (N=751) Stable OP 1 RCT (N=7896)	ACS: ROB (-1) Imprecision (-1) Stable OP Consistency unknown Imprecision (-1)	Suspected ACS (CP, SOB, palpitations) CCTA vs. SPECT 1 RCT, 0.5% vs. 16% RR 0.03 (0.004 to 0.24) CCTA vs. Stress Echo 1 RCT, 0% vs. 3% Stress-related symptoms CCTA vs. stress nuclear imaging Stress-induced symptoms (unspecified) 0% vs. 0.1% Dipyridamole, adenosine related: 0% vs. 0.2% Conclusions: These symptoms are consistent with expected responses to the medications used for stress imaging and are not generally considered adverse events.	⊕⊕◯◯ LOW
Arrythmias: Rapid atrial fibrillation (AF) Ventricular tachycardia Bradyarrhythmia	Index test up to 24 hours	Stable outpatients 1 RCT (N=7896) Suspected ACS 1 RCT (N=1370)	ROB (-1) (Suspected ACS) Both populations Unknown consistency Imprecision (-1)	CCTA vs. functional testing Stable outpatients Rapid AF 0% vs. 0% Ventricular Tachycardia: 0% vs. 0.2% (nuclear stress test) Suspected ACS Bradyarrhythmia: 0.1% vs. 0.2%	⊕◯◯◯ INSUFFICIENT

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KQ 3 Safety: Radiation exposure

- Variably reported; only rough estimates of difference possible
- Exposure generally less with CCTA vs. SPECT at index test
- Cumulative radiation may be higher with CCTA as index test, but results are mixed.
- It is unclear if some differences between testing arms would impact clinical decisions

Outcome	Follow-up	Studies	Downgrade	Conclusion Effect Estimate (95% CI)	Quality (SOE)
Radiation exposure	Index Test	5 RCTs (N=7896) Stable OP 3 RCTs Suspected ACS 3 RCTs	ROB (-1) Inconsistent (-1)	Conclusions: 5/6 RCTs of CCTA vs. *SPECT*, CCTA was associated with a lower radiation dose (estimated range 1.30 mSv to 11.9 mSv)	⊕⊕◯◯ LOW
Radiation exposure	Cumulative	9 RCTs; N=13,984 Stable OP 3 RCTs Suspected ACS 6 RCTs	ROB (-1) Inconsistent (-1)	Conclusions: Results are somewhat mixed but suggest that cumulative radiation may be higher when CCTA is the initial test. Estimated differences between arms reported higher for CCTA 1.9 mSv to 9 0 mSv	⊕⊕◯◯ LOW

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KQ 3 Safety

Incidental findings following CCTA

Outcome	Studies	Downgrade	Conclusion Effect Estimate (95% CI)	Quality (SOE)
Incidental findings	3 RCTs 2 systematic reviews 4 Retro cohorts	ROB (-2) Inconsistent (-1)	"Any" incidental finding range: (28% to 44%) **Findings considered "potentially significant" "clinically significant" or "required follow-up" range: 4.9% to 16%** **Conclusion**: Incidental findings are common; pulmonary findings were most common. There is wide range of findings considered potentially important that would likely result in the need to follow-up and/or would require additional testing.	⊕⊕◯◯ LOW

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KQ 4 Differential Effects

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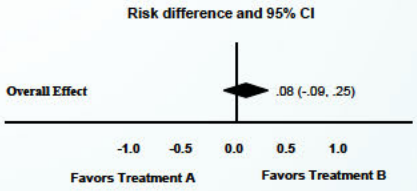
KQ 4: Differential effects (HTE, Modification)

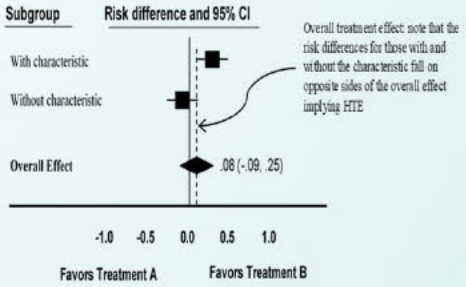


Does the effect of an intervention (or test) on an outcome vary by levels of another variable?

HTE/EM: defines an association between the variable (modifier) and the causal effect of the intervention on the outcome

Need to consider:

- A priori specification, hypothesis
- Role of chance (test for interaction)
- Number of analyses
- Prior evidence
- Sample size
- Hypothesis generating



Figures from: Dettori JR, EBSJ 2011;2(2):7-10

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KQ 4 differential effects: CCTA vs. functional testing

Subgroup, factor	Population Studies	Outcomes and Findings
Male, female	Suspected ACS 1 RCT (ROMICAT II)	There was no modification by sex for • ICA referral or downstream testing • Revascularization • Repeat ED visit or hospitalization for chest pain
	Stable OP 1 RCT (PROMISE)	Potential modification by sex for • Test positive rate: higher w/CCTA for males, lower in females (interaction p<0.001) There was not modification by sex for • Cumulative radiation dose (≤90 days)
DM, no DM	Suspected ACS 1 RCT (ROMICAT II)	Patients with DM had higher • Rates of downstream testing w/CCTA at index, 28-day follow-up (interaction p ≤0.001) • Mean cumulative radiation with CCTA (interaction p=0.04) There was no modification by DM for • ICA referral, revascularization
	Stable OP 1 RCT (PROMISE)	There was no modification by DM for • Test positivity rate • ICA within 90 days of index test • Revascularization

- Confidence in findings: very low
- Sex and diabetes status may modify testing results for some outcomes; findings are hypothesis generating are require verification
- Age, type of angina and race did not modify the effect of testing on outcomes evaluated (see report); findings for most were insufficient

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Summary: CCTA vs. Functional Testing

KQ 1. Impact on clinical outcomes

- MI: No clear difference (Moderate SOE)
- All-cause mortality: No difference (Moderate SOE)
- Cardiac mortality: Insufficient evidence

KQ 2. Clinical decision making

- ICA referral: ↑ with CCTA (Moderate SOE)
- Additional testing: No difference (Low SOE)
- Revascularization and PCI: ↑ with CCTA (Moderate SOE)
- Medication initiation/change: Insufficient evidence
- Hospitalization:
  - No difference after index test for suspected ACS (High SOE) or at any time for stable OP (Moderate SOE)
  - Insufficient evidence at index test for suspected ACS

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Summary: CCTA vs. Functional Testing

KQ 3. Safety (Low SOE)

- Test-specific AEs – Rare
- Radiation:
  - Index test, ↓ for CCTA
  - Cumulative, ↑ for CCTA
- Incidental findings: Common

KQ 4. Differential effectiveness or safety

- Sex and diabetes may modify testing; limited confidence, verification needed

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Summary: Other CT-related

FFRct: 1 prospective NRS (see full report)

- KQ 1 and 2: Insufficient evidence
- Safety: CCTA + FFRct, greater cumulative radiation (Low SOE)

CT perfusion: No prospective comparative studies identified.

CCTA vs. direct referral to ICA: (see full report)

- KQ1: Clinical outcomes: NS difference in MI, all-cause mortality (Low SOE)
- KQ 2: CCTA associated with ↓ risk of ICA without obstructive CAD and of PCI/any revascularization but ↑ in additional testing (Moderate SOE for all)
- KQ 3: Safety – 2 major AEs (bleeding 0.4%) with ICA (Low SOE)

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SPECT

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Patient characteristics: SPECT vs. functional testing

SPECT vs. Stress Echocardiography 2 RCTs (N=679)	SPECT vs. exercise ECG 2 RCTs (N=1,281)
Mixed suspected or known (24%-27%) CAD	Suspected CAD (known CAD excluded)
1 stable outpatients (referred for ICA) 69% high, 31% low pretest risk* 1 acute ED presentation (hospitalized) Pretest risk: NR	Stable outpatients 84%-100% intermediate-to-high pretest risk
Mean age 57-62 years, female 30%-54% female, Caucasian 75% (1 trial)	Mean age 60-63 years; female 44%-100%; Caucasian 52%-87%
Chest pain type NR	Presenting symptoms, 1 RCT (100% female): typical angina (60%), atypical angina (9%), nonspecific angina (28%), dyspnea (51%)
Cardiac risk factors: hypertension (58%-76%), hyperlipidemia (48%-78%), diabetes (12%-39%), family hx CAD (26%, 1 RCT), smoking hx (43%, 1 RCT) cerebrovascular accident (6%-8%)	Cardiac risk factors: hypertension (50%-53%), hyperlipidemia (55%, 1 RCT), diabetes (13%-17%) and family history of CAD (43%-47%), smoking history (14%-45%*)
Industry funding (1 RCT, GE healthcare) and government funding (1 RCT)	Industry funding both RCTs (research grants also in 1).

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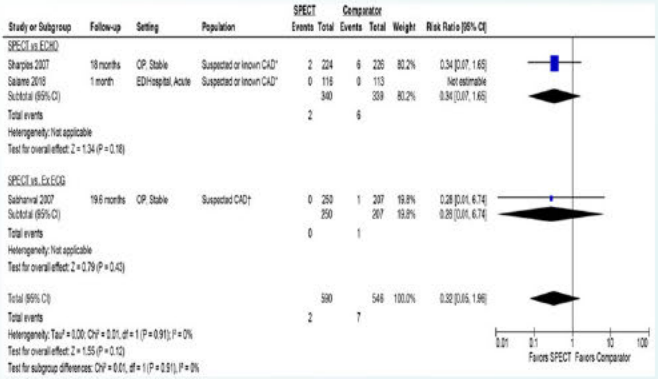
Results KQ 1, MI: SPECT vs. functional testing, all populations



SOE: Insufficient: 4 RCTs total (N=1,908);

- Pooled estimates (2 RCTs, N=907); Risk: 0.3 vs. 1.3 per 100 patients, 1 additional RCT: no events in either group
- 1 RCT, SPECT vs. ECG (N=772): 0.4 per 100 patients (NR by arm)

Analytics

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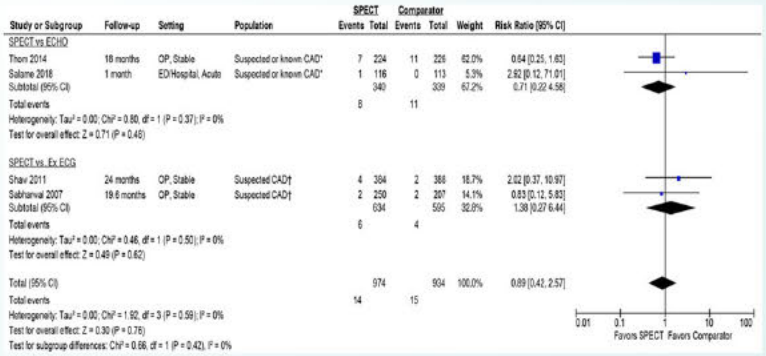
Results KQ 1, Mortality: SPECT vs. functional testing, all populations

No difference in all-cause mortality (SOE: Low)

Pooled estimates (4 RCTs, N=1,908); Risk: 1.4 vs. 1.6 per 100 patients



Cardiac mortality (SOE: Insufficient)

3 RCTs total (N=1,679); Pooled estimates (2 RCTs, N=907); Risk 0.3 vs. 1.3 per 100 patients

- 1 RCT, SPECT vs. ECG (N=772): 0.4 per 100 patients (NR by test arm)

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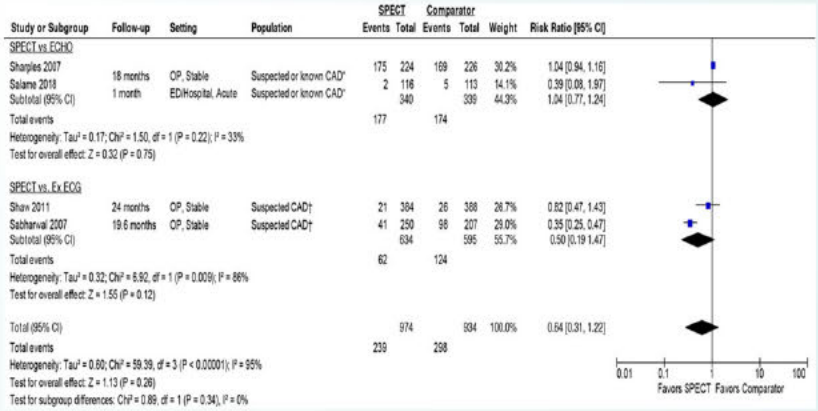
Results KQ 2, ICA: SPECT vs. functional testing, all populations



No difference, SOE: Low (ROB, inconsistency)

4 RCTs; N=1,908; Risk: 24.5 vs. 31.9 per 100 patients

RR 0.64 (0.31 to 1.22)

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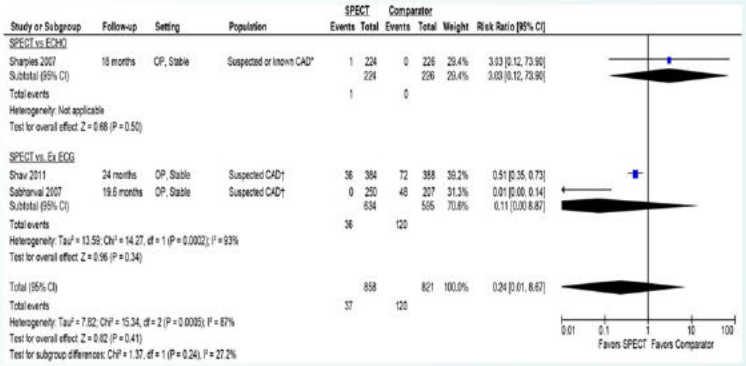
KQ 2, Any additional NIT: SPECT vs. functional testing, all populations



SOE: Insufficient (ROB, inconsisency, imprecision)

Pooled estimates (3 RCTs; N=1,679); Risk: 4.3 vs. 14.6 per 100 patients

- SPECT vs. Echo (1 RCT; N=450): Risk, 0.4 vs. 0 per 100 patients
- SPECT vs. ECG (2 RCTs, N=1,229): Risk, 5.7 vs. 20.2 per 100 patients

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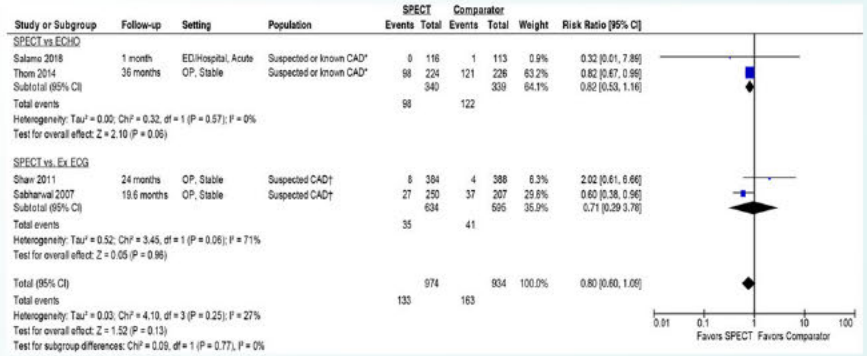
KQ 2, Any revascularization: SPECT vs. functional testing, all populations



No difference in revascularization, SOE Moderate (ROB)

4 RCTs (N=1,908); Risk: 13.7 vs. 17.5 per 100 patients

No difference when PCI and CABG considered separately

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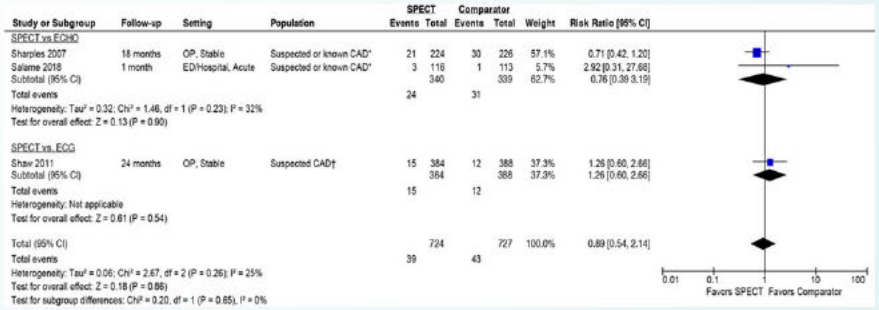
Results KQ 2, Cardiac-related hospitalization and ED revisit: SPECT vs. functional testing, all populations

Cardiac-related hospitalization (SOE: Low)

Pooled estimates (3 RCTs, N=1,451); Risk: 5.4 vs. 5.9 per 100 patients



ED re-visit (SOE: Low)

1 RCT (N=229); Risk: 2.6 vs. 2.7 per 100 patients; RR 0.97 (95% CI 0.20 to 4.73)

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Results KQ 1: SPECT vs. NICE guideline-directed care (GDC) and clinical assessment only

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
MI	Median 16 mos.	1 RCT (N=721) SPECT vs. NICE GDC (stable, OP)	Unknown consistency Imprecision (-2)	Risk: 0.4 vs. 0.8 per 100 patients, RR 0.50 (95% CI 0.07 to 3.52)	⊕◯◯◯ INSUFFICIENT
All-cause mortality cumulative				Risk: 0.6 vs. 1.3 per 100 patients, RR 0.50 (95% CI 0.10 to 2.45)	
Cardiac mortality cumulative	12, median 16 mos.	2 RCTs (N=2,229) 1 SPECT vs. NICE GDC (stable, OP) 1 SPECT vs. clinical exam (acute, ED)	ROB (-1), Imprecision (-2)	Risk: 0.4 vs. 0.1 per 100 patients RR 2.04 (95% CI 0.25 to 19.09), I^2=0%	

➢ **Insufficient**

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Results KQ 2, ICA: SPECT vs. NICE guideline-directed care (GDC) and clinical assessment only

ICA referral lower with SPECT (2 RCTs, N=2,229); SOE: Low (ROB, inconsistency)

Risk: 10.2 vs. 21.1 per 100 patients; RD –11.1% (95% CI –14.4% to –7.8%)

- **ICA showing no obstructive CAD** (SPECT vs. clinical assessment, N=1,508): Risk: 21.9 vs. 39.3 per 100 patients, RR 0.56 (95% CI 0.32 to 0.96), RD –17.4% (95% CI –33.3% to –1.4%)
- **Unnecessary ICA** (SPECT vs. NICE GDC, N=721): Risk: 7.1 vs. 28.8 per 100 patients, RR 0.25 (95% CI 0.17 to 0.36), RD –21.7% (95% CI –27.9% to –15.5%)
- **SOE Low** for both

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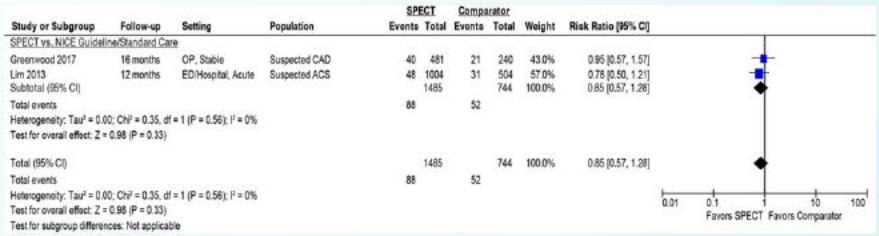
Results KQ 2, Any revascularization: SPECT vs. NICE guideline-directed care and clinical assessment only

No difference in revascularization (SOE Low)

Pooled estimates, 2 RCTs (N=2,229):

Risk: 5.9 vs. 7.0 per 100 patients



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Results KQ 2, Any additional NIT and hospitalization: SPECT vs. clinical assessment only

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Additional NIT (any)	12 mos.	1 RCT (N=1,508) Acute, ED setting	ROB (-1), Consistency unknown	Risk: 12.1 vs. 68.3 per 100 patients, RR 0.18 (95% CI 0.15 to 0.21), RD –56.2% (95% CI –60.7% to –51.7%)	⊕⊕◯◯ LOW
Hospitalization	Index			Risk: 10.2 vs. 18.5 per 100 patients, RR 0.55 (95% CI 0.42 to 0.71), RD –8.3% (95% CI –12.2% to –4.4%)	

- ↓ risk with SPECT for both outcomes

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Results KQ 1: SPECT vs. ICA

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
MI	18 mos.	1 RCT (N=446) Stable, OP	Unknown consistency Imprecision (-2)	0.9 vs. 0 per 100 patients; all admissions for acute MI	⊕◯◯◯ INSUFFICIENT
All-cause mortality cumulative	72 mos.			18 months 1.8 vs. 1.8 per 100 patients, RR 0.99 (95% CI 0.25 to 3.91) 72 months 3.1 vs. 3.2 per 100 patients, RR 0.99 (95% CI 0.35 to 2.78)	
Cardiac mortality cumulative	18 mos.			2.2 vs. 1.4 per 100 patients, RR 1.65 (95% CI 0.40 to 6.83)	

- SOE Insufficient

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KQ 2: SPECT vs. ICA

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Additional NIT (any)	Unclear	1 RCT (N=448) Stable, OP	Unknown consistency Imprecision (-2) NIT	0.4 vs. 3.6 per 100 patients, RR 0.12 (95% CI 0.02 to 0.98), RD –3.2% (95% CI –5.8% to –0.6%)	NIT ⊕◯◯◯ INSUFFICIENT
Revascularization (any)	36 mos.		Imprecision (-1) Revasc. and hospitalization	Index 30.4 vs. 34.2 per 100 patients, RR 0.89 (95% CI 0.68 to 1.16) 36 months (cumulative) 43.8 vs. 53.2 per 100 patients, RR 0.82 (95% CI 0.68 to 0.99) RD –9.4% (95% CI –18.6% to –0.2%)	Revasc., hosp. ⊕⊕◯◯ LOW
Hospitalization (chest pain)	18 mos.			8.5 vs. 6.3 per 100 patients, RR 1.35 (95% CI 0.69 to 2.62)	

- ↓ any revascularization SOE low, NIT insufficient
- **No difference** b/w testing arms for cardiac hospitalization

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Results KQ 3: SPECT

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Test-related AEs	Median 16 mos.	1 RCT (N=721) SPECT vs. NICE GDC (stable, OP)	Unknown consistency Imprecision (-1)	Test-related AEs appear to be rare w/ SPECT. 5 test-related medical AEs; none following SPECT.	⊕⊕◯◯ LOW
Radiation exposure	Index	1 RCT (N=722) SPECT vs. Ex. ECG Stable, OP (females)	Unknown consistency ROB (-1) Imprecision (-1)	Mean exposure, 14 mSv (no SD or CI)	⊕◯◯◯ INSUFFICIENT
AEs related to regadenoson and dipyridamole	NR	3 studies (N=380, 604 AEs) 1 retro cohort 2 case series Suspected or known CAD	ROB (-1), Imprecision (-1)	2%–13% of patients Dipyridamole 5%–37% of AEs Regadenoson 4%–53% of AEs Many may be expected responses to these drugs	⊕⊕◯◯ LOW

Analytics

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Summary: SPECT vs. Other functional tests

KQ 1. Impact on clinical outcomes

- MI, cardiac mortality: Insufficient evidence
- All-cause mortality: NS difference vs. ETT or Echo (Low SOE)

KQ 2. Clinical decision making

- ICA referral: NS difference (Low SOE)
- Additional testing: Insufficient evidence
- Revascularization: NS difference (Moderate SOE)
- Cardiac hospitalization, ED revisit: NS difference (Low SOE)

KQ 3. Safety

- Test-specific AEs – Rare (Low SOE)
- Radiation: Insufficient evidence

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Summary: SPECT vs. other comparators (NICE Guideline directed care, clinical assessment, ICA)

KQ 1. Impact on clinical outcomes (all comparators)

- MI, cardiac and all-cause mortality: Insufficient evidence

KQ 2. Clinical decision making

- ICA referral:
  - NICE GDC, clinical assessment: ↓ with SPECT (Low SOE)
- Additional NIT:
  - Clinical assessment alone: ↓ with SPECT (Low SOE)
  - ICA: insufficient evidence
- Revascularization:
  - NICE GDC, clinical assessment: NS difference (Low SOE)
  - ICA: ↓ with SPECT (Low SOE)
- Hospitalization:
  - Clinical assessment alone: ↓ with SPECT (Low SOE)
  - ICA: NS difference (Low SOE)

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Stress Echocardiography

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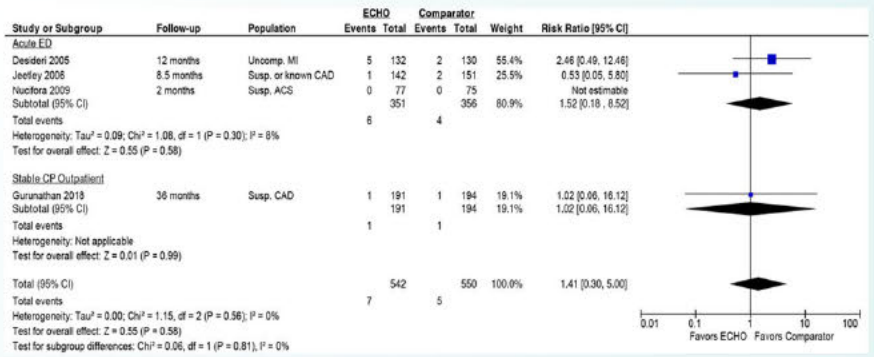
KQ 1, MI: Stress Echo vs. Exercise ECG, all populations



5 RCTs total (N=1,250); SOE: Insufficient

- Pooled estimates (3 RCTs, N=940); Risk: 1.3 vs. 0.9 per 100 patients
  - 1 RCT: no events in either group
- 1 RCT in stable OPs (N=158): 0.3 per 100 patients (NR by test arm)

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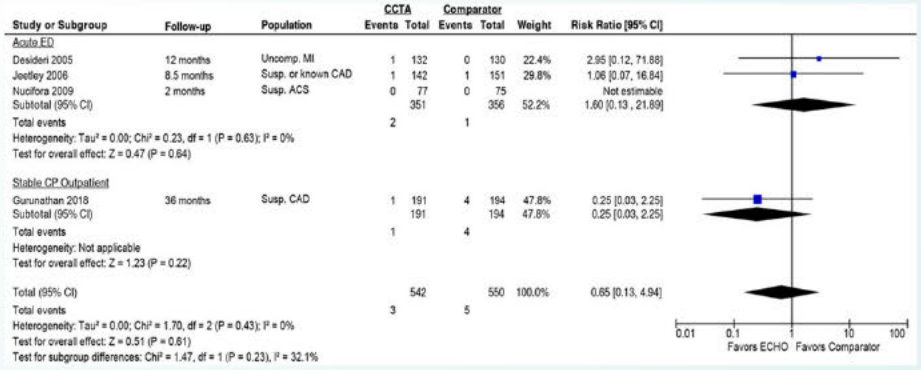
KQ 1, Mortality: Stress Echo vs. Exercise ECG, all populations

All-cause mortality (SOE: Insufficient)

Pooled estimates (3 RCTs, N=940) [0 events in 1 RCT]; Risk: 0.6 vs. 0.9 per 100 patients



Cardiac mortality (SOE: Insufficient)

1 RCT in stable OPs (N=385); Risk 0.5 vs. 0 per 100 patients

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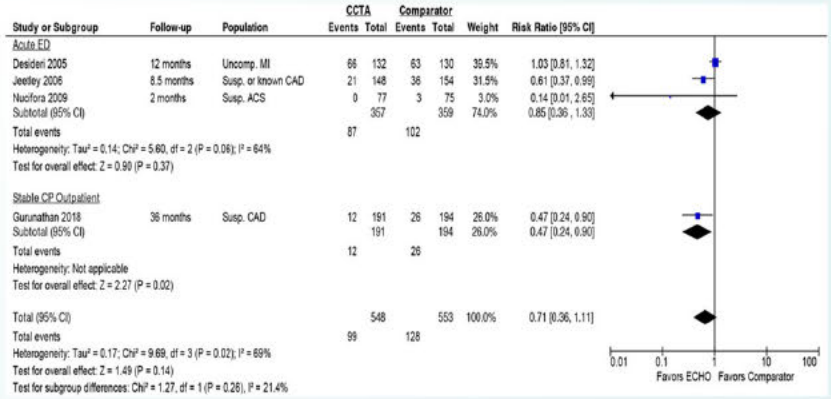
KQ 2, ICA: Stress Echo vs. Exercise ECG, all populations



Stable OPs: ↓ risk of ICA with Stress Echo (1 RCT)

Acute/ED patients: no difference

SOE: Low

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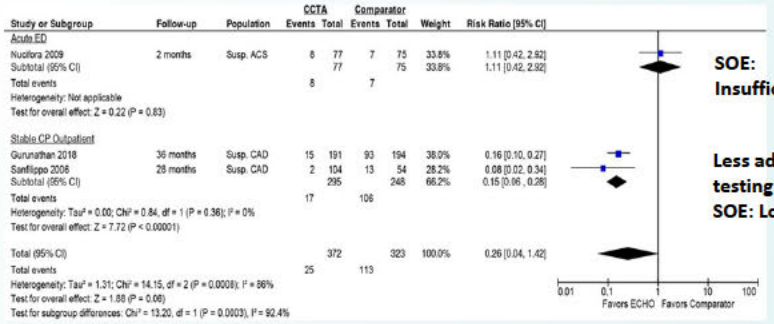
KQ 2, Any additional NIT: Stress Echo vs. Exercise ECG, all populations



SOE: Insufficient

Less additional testing w/Echo
SOE: Low

Acute/ED patients: Insufficient

Stable OPs: ↓ risk of additional NIT with Stress Echo

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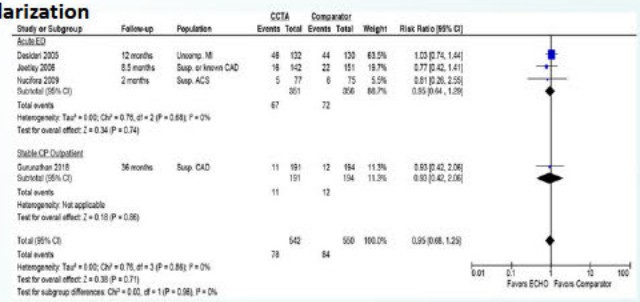
Results KQ 2, Any revascularization and Hospitalization: Stress Echo vs. Exercise ECG, all populations

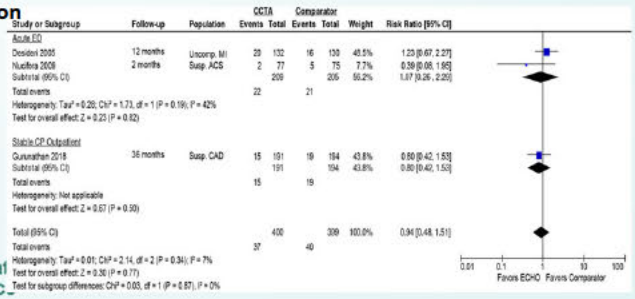
Any revascularization



No difference

SOE: Moderate

Hospitalization



No difference

SOE: Moderate

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KQ 1: Stress Echocardiography vs. ICA

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
MI	18 mos.	1 RCT (N=448) Stable, OP	Unknown consistency Imprecision (-2)	2.7 vs. 0 per 100 patients, p=0.01; all admissions for acute MI	⊕◯◯◯ INSUFFICIENT
All-cause mortality cumulative	72 mos.			18 months 2.7 vs. 1.8 per 100 patients, RR 1.47(95% CI 0.42 to 5.15) 72 months 4.9 vs. 3.2 per 100 patients, RR 1.54 (95% CI 0.61 to 3.91)	
Cardiac mortality cumulative	18 mos.			0.4 vs. 1.4 per 100 patients, RR 0.33 (95% CI 0.03 to 3.12)	

- SOE Insufficient

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KQ 2: Stress Echocardiography vs. ICA

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Additional NIT (any)	Unclear	1 RCT (N=448) Stable, OP	Unknown consistency Imprecision (-2) (NIT) Imprecison (-1) for Revasc., hosp.	0 vs. 3.6 per 100 patients, p=0.01	⊕◯◯◯ INSUFFICIENT
Revascularization (any)	36 mos.			Index Risk: 35.4 vs. 34.2 per 100 patients, RR 1.03 (95% CI 0.80 to 1.33) 36 months (cumulative) Risk: 53.5 vs. 53.2 per 100 patients, RR 1.01 (95% CI 0.85 to 1.20)	⊕⊕◯◯ LOW
Hospitalization (chest pain)	18 mos.			Risk: 10.6 vs. 6.3 per 100 patients, RR 1.68 (95% CI 0.89 to 3.17)	

- No difference b/w testing arms for Revascularization or Hospitalization

Stress Echo vs. standard care: 1 poor quality RCT (N=132), all outcomes: SOE Insufficient

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KQ 3: Stress Echocardiography

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Any complication	2 mos.	1 RCT (N=152) SPECT vs. Ex. ECG Uncomplicated MI	ROB (-1), Unknown consistency Imprecision (-1)	No test-related complications	⊕◯◯◯ INSUFFICIENT
Dobutamine, dipyridamole- and adenosine-related AEs	Index	Dobutamine: 11 case series (N range, 86–2799)* Dipyridamole: 3 case series (N=946)* Adenosine: 1 case series (N=1429)*	ROB (-2), Unknown consistency	**Potentially life-threatening AEs:** 0% to ≤0.1% **Any arrythmia/tachycardia:** 0%–18% (dobutamine only) **AF, VF, bradycardia:** 0%–1.2% **Hypotension:** 0%–12.5% **Hypertension:** 0%–7.5% **Other/general†:** 0%–31%	⊕⊕◯◯ LOW
Noniodinated contrast	Index	3 studies (N=9,821) [2 comparative cohorts (N=6,750) and 1 database study (N=3,071)]	ROB (-2), Unknown consistency	**Definite or suspected contrast-related adverse events:** 1.3% (41/3071) and 2 2% (68/3071), respectively (1 database study) **Allergic reaction:** <0 5% of patients (2 cohorts, 1 database study)	⊕⊕◯◯ LOW

Some symptoms/events (e.g., dyspnea, flushing, etc.) are mild, transient and common expected reactions to stress agents and may not be considered AEs

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Summary: Stress Echo vs. ETT

KQ 1. Impact on clinical outcomes

- MI, all-cause and cardiac mortality: Insufficient evidence

KQ 2. Clinical decision making

- ICA referral (Low SOE):
  - Stable OP: ↓ risk of ICA with Stress Echo (1 RCT)
  - Acute/ED patients: NS difference
- Additional NIT:
  - Stable OP: ↓ risk with Stress Echo (Low SOE)
  - Acute/ED patients: Insufficient evidence
- Revascularization, Hospitalization: NS difference (Moderate SOE)

KQ 3. Safety

- Serious test-specific AEs – Rare (Low SOE)

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Summary: Stress Echo vs. SOC and ICA

KQ 1. Impact on clinical outcomes

- MI, all-cause and cardiac mortality: Insufficient evidence

KQ 2. Clinical decision making

- ICA referral: Insufficient evidence
- Additional NIT: Insufficient evidence
- Revascularization, Hospitalization:
  - Stress Echo vs. SOC/UC: Insufficient evidence
  - Stress Echo vs. ICA: NS difference either outcome (Low SOE)

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PET

Aggregate Analytics

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KQs 1, 2 and 3: PET vs. SPECT

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
MI; all-cause mortality (cumulative)	12 mos.	1 RCT (N=322) Known CAD, new or worsening symptoms	Unknown consistency Imprecision (-2) Imprecision (-1) ICA, Revasc.	**MI:** Risk, 0 vs. 1.2 per 100 patients, p=NS **All-cause mortality:** Risk, 1 vs. 1 2 per 100 patients; RR 0.50 (95% CI 0.04 to 5.46)	⊕◯◯◯ INSUFFICIENT
ICA (cumulative)				**3 months:** Risk, 20.5 vs. 15.5 per 100 patients; RR 1.32 (95% CI 0.82 to 2.11) **6 months:** Risk, 22.4 vs. 18.6 per 100 patients; RR 1.20 (95% CI 0.78 to 1.85) **12 months:** Risk, 28.6 vs. 28.0 per 100 patients; RR 1.02 (95% CI 0.72 to 1.45)	
Any revascularization (cumulative)				**3 months:** Risk, 11.2 vs. 9.9 per 100 patients; RR 1.13 (95% CI 0.60 to 2.13) **6 months:** Risk, 12.4 vs. 11.8 per 100 patients; RR 1.05 (95% CI 0.58 to 1.90) **12 months:** Risk, 15.5 vs. 14.9 per 100 patients; RR 1.04 (95% CI 0.62 to 1.74)	⊕⊕◯◯ LOW
Medication change				3 months: Risk, 26 vs. 23 per 100 patients; RR 1.11 (95% CI 0.75 to 1.63)	

- **Known CAD:** Insufficient evidence for MI, all-cause mortality; NS difference in ICA, revascularization (SOE Low)
- **Mixed suspected, known CAD**: Cardiac death: Insufficient, 1 poor RCT (N=210)
- **Safety (KQ3):** no evidence

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KQ 5 Cost-effectiveness

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KQ 5 Cost-effectiveness: All modalities
3 SRs, 11 additional primary economic studies

- Firm conclusions regarding cost-effectiveness are not possible
- Most studies evaluated testing strategies vs. individual tests and were from health systems outside of the U.S.
- Results across studies were mixed likely due to substantial heterogeneity (data sources, modeling, clinical pathways, etc.)
- CE/ICERs varied based on test sequencing, pre-test CAD probability, assumed accuracy of various tests
- Common limitations:
  - Insufficient modeling of: indeterminant tests, test accuracy based on sequencing, FN/FP results, potential AEs, incidental finding f/u
  - Extrapolation to lifetime time horizon;
  - Impact of tests on clinical outcomes is indirect
  - Assumed 100% accuracy of ICA

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Summary

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Summary: CCTA vs. any functional test – Efficacy

Outcome	All patients	ED/similar setting	Stable outpatients
Key Question 1: Clinical outcomes			
MI	Θ* Moderate SOE (14; N=21,661)	Θ (10; N=5,977)	Θ * (4; N=15,684)
All-cause death	Θ Moderate SOE (11; N=18,935)	Θ (7; N=4,001)	Θ (4; N=14,934)
Cardiac death	Insufficient evidence	Insufficient evidence	Insufficient evidence
Key Question 2: Decision-making			
ICA	↑† Moderate SOE (19; N=22,335)	↑ (14; N=7,227)	Θ* (4; N=15,107)
Any additional NIT	Θ Low SOE (17; N=11,595)	Θ (13; N=6,491)	Θ (4; N=5,104)
Any revascularization	↑ Moderate SOE (19; N=23,124)	↑ (13; N=7,014)	↑ (19; N=16,110)
Hospitalization	Data not pooled	Index visit: Insufficient evidence Θ High SOE 1-6.5 mos. (9; N=5,144) ≥12 mos. (6; N=3,624)	Any timepoint: Θ Moderate SOE (4; N=14,810)
Subsequent ED visit	NR	Θ High SOE 1-6.5 mos. (7; N=4,294) ≥12 mos. (5; N=2,855)	NR
Medication change	Insufficient evidence	Insufficient evidence	Insufficient evidence

Aggregate Analytics Θ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: other CCTA – Efficacy

Outcome	CCTA vs. ICA
KQ 1: Clinical outcomes	
MI	Θ Moderate SOE (2; N=1,832)
All-cause death	Θ Moderate SOE (2; N=1,832)
Cardiac death	Insufficient evidence
KQ 2: Decision making	
ICA	Not showing obstructive CAD ↓ Moderate SOE (2; N=1,832)
Any additional NIT	↑ Moderate SOE (1; N=1,503)
Any revascularization	↓ Moderate SOE (2; N=1,832)
Hospitalization	Θ Moderate SOE (2; N=1,832)
Subsequent ED visit	NR
Medication change	NR

CCTA FFR

1 prospective cohort (N=584)
- vs. planned noninvasive test (any) (N=204)
- vs. planned ICA (N=380)

SOE: Insufficient for all clinical and decision-making outcomes

SOE: Low – cumulative radiation exposure
- ↑ with CCTA FFR vs. any NIT; no difference vs. ICA

Aggregate Analytics Θ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: CCTA vs. any functional test – Safety

Outcome	All patients
Any major test-related AE	ϴ Low SOE (0%; 3 RCTs, N=10,270)
Hospital admission for test-related complication	ϴ Low SOE (0% vs. 0.1%; 1 RCT, N=9,470)
Nephropathy	Insufficient evidence
Transient creatinine increase	ϴ Low SOE (0.2%–1% vs. 0%–0.4%; 2 RCTs, N=1,500)
Chest pain, shortness of breath, or palpitations	↓ Low SOE (0%–0.5% vs. 3%–16%; 2 RCTs, N=751)
Stress-related symptoms and events; dipyridamole, adenosine-related events	ϴ Low SOE (0% vs. 0.1%–0.5%; 1 RCT, N=7,896)
Arrythmias (rapid AF, ventricular tachycardia, bradyarrhythmia)	Insufficient evidence
Radiation exposure – Index test (CCTA vs. SPECT)	↓ Low SOE (estimated range, 1.3–11.9 mSv; 5/6 RCTs, N=7,981)
Radiation exposure – Cumulative	↑ Low SOE (range of differences 1.9–9.0 mSv; 9 RCTs; N=13,984)
Incidental findings: "potentially serious" or requiring additional imaging *(CCTA arms only)*	Common, Low SOE ("any": 28%–44%; "potentially serious, required follow-up": 5%–16%; 3 RCTs)
Extravasation of contrast *(CCTA arms only)*	Rare, Low SOE (stable OP: 0.3%-0.4%; ED: 2%; 3 RCTs, N=6,911)
Mild contrast-related reaction, allergic reaction, skin rash/reaction, pruritis *(CCTA arms only)*	Rare, Low SOE (stable OP: 0.5%; ED: 1.2%; 5 RCTs, N=6,980)

Aggregate Analytics

ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: CCTA vs. ICA – Safety

Major AEs were rare, there were no differences between testing arms; RCTS may have been underpowered.

CCTA was associated with fewer minor procedural AEs (data not shown).

SOE LOW

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Major adverse events	≤48 hours, median 12 months	2 RCTs (N=1,832) Suspected CAD: 1 stable OP; 1 stable and acute, atypical chest pain	Imprecision (-2)	**Any complications prolonging hospital stay** No events in either test arm (1 RCT; N=327) **Major bleeding** Risk: 0 vs. 0.3 per 100 patients (1 RCT; N=1,503)	⊕⊕◯◯ LOW

Aggregate Analytics

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Summary: SPECT – Efficacy

Outcome	SPECT vs. Any functional test	SPECT vs. NICE guideline-directed care/clinical assessment	SPECT vs. ICA
Key Question 1: Clinical outcomes			
MI	Insufficient evidence	Insufficient evidence	Insufficient evidence
All-cause death	ϴ Low SOE (4; N=1,908)	Insufficient evidence	Insufficient evidence
Cardiac death	Insufficient evidence	Insufficient evidence	Insufficient evidence
Key Question 2: Decision-making			
ICA	ϴ* Low SOE (4; N=1,908)	↓ Low SOE (2; N=2,229)	NA
ICA showing no obstructive CAD	NR	↓ Low SOE (1; N=1,508; clinical)	NR
Unnecessary ICA	NR	↓ Low SOE (1; N=721; NICE)	NR
Any additional NIT	Insufficient evidence*	↓ Low SOE (1; N=1,508; clinical)	Insufficient evidence
Any revascularization	ϴ* Moderate SOE (4; N=1,908)	ϴ Low SOE (2; N=2,229)	↓ Low SOE (1; N=448)
Hospitalization	ϴ Low SOE (3; N=1,451)	↓ Low SOE (1; N=1,508; clinical)	ϴ Low SOE (1; N=448)
Subsequent ED visit	ϴ Low SOE (1; N=229)	NR	NR
Medication change	NR	NR	NR

ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: SPECT – Safety

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Test-related AEs	Median 16 mos.	1 RCT (N=721)	Imprecision (-2)	None following SPECT	⊕⊕◯◯ LOW
Radiation exposure	Index	1 RCT (N=722)	ROB (-1), imprecision (-2)	Mean ionizing radiation: 14 mSv (SPECT) vs. NA (exercise ECG)	⊕◯◯◯ INSUFFICIENT
AEs related to regadenoson and dipyridamole	NR	1 retro cohort, 2 case series (N=380 patients, 604 AEs)	ROB (-1), imprecision (-1)	Range 2% to 13% of patients Dipyridamole 5% to 37% of AEs Regadenoson 4% to 53% of AEs most are likely expected, minor and transient	⊕⊕◯◯ LOW

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Summary: Stress Echocardiography – Efficacy

Outcome	Stress Echo vs. Exercise ECG	Stress Echo vs. Standard Care	Stress Echo vs. ICA
Key Question 1: Clinical outcomes			
MI	Insufficient evidence	Insufficient evidence	Insufficient evidence
All-cause and cardiac death	Insufficient evidence	Insufficient evidence	Insufficient evidence
Key Question 2: Decision-making			
ICA	Stable outpatients: ↓ Low SOE (1, N=385)	Insufficient evidence	NA
	ED/similar setting*: Θ Low SOE (3; N=716)		
Any additional NIT	Stable outpatients: ↓ Low SOE (1, N=385)	Insufficient evidence	Insufficient evidence
	ED/similar setting†: Insufficient evidence		
Any revascularization	Θ Moderate SOE (4; N=1,092)	Insufficient evidence	Θ Low SOE (1, N=385)
Hospitalization	Θ Moderate SOE (3; N=799)	Insufficient evidence	Θ Low SOE (1, N=385)
Subsequent ED visit	NR	NR	NR
Medication change	NR	NR	NR

Aggregate Analytics

Θ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: Stress Echocardiography – Safety

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Any complication	2 mos.	1 RCT (N=152)	ROB (-1), imprecision (-2)	None occurred (stress echo vs. exercise ECG)	⊕◯◯◯ INSUFFICIENT
Dobutamine-related AEs	NR	11 case series (N range, 86–2799)*	ROB (-2)	Major AEs (death, MI, UA, CVA, acute pulmonary edema): ≤0.1% across all outcomes	⊕⊕◯◯ LOW
				Arrythmia-related AEs • Any arrythmia and tachycardias: 0%–18% • Atrial fibrillation and bradycardia: ≤1%	
				Hypotension: 0.1%–12.5% Hypertension: 0%–7.5%	
				General, other (e.g., chest pain, nausea/vomiting, headache, dyspnea and tremors): 0%–31%	
Dipyridamole- and adenosine-related AEs	NR	4 case series (N range, 109–1429)	ROB (-2)	No major AEs; minor AEs are not uncommon and occurred with variable frequency and ranged from 0.2% (vomiting and nausea) to 43% (headache).	
Noniodinated contrast-related AEs		2 cohorts (N=6,750), 1 database study (N=3,071)	ROB (-2)	Definite, 1.3% (41/3071) and Suspected, 2.2% (68/3071) AEs [1 database study] Allergic reaction: <0.5%	

Some symptoms/events (e.g., dyspnea, flushing, etc.) are mild, transient and common expected reactions to stress agents and may not be considered AEs

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Summary: PET – Efficacy and Safety

Outcome	PET vs. SPECT
MI; all-cause death; cardiac death	Insufficient evidence
ICA; any revascularization; medication change	ϴ Low SOE (1; N=322)

- KQ3 (Safety): No evidence

Aggregate Analytics ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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KQ 5 Cost-effectiveness: All tests

- Firm conclusions regarding cost-effectiveness are not possible
- Results across studies were mixed
- CE/ICERs varied based on test sequencing, pre-test CAD probability, assumed accuracy of various tests

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Considerations

Pathology considerations

- Identification and degree of obstruction do not always correlate to patient symptoms, presence or degree of ischemia or functional impact
- Ischemia may be present in the absence of obstruction and would not be identified by anatomic testing
- Patient pre-test probability and other factors impact testing choice

Applicability

- There is substantial heterogeneity across studies regarding patients, determination of pre-test risk, equipment, testing and study methods
- All imaging tests require substantial expertise. Tests performed in the RCTs reflect this. The same level of expertise may not be available in all clinical settings. Similarly, state of the art equipment may not be available in all settings.
- Stress echo, SPECT are established modalities for CAD diagnosis; Fewer trials, reflect older technology and research methods; different research funding opportunities vs. CCTA
- All imaging modalities are clinically considered to be better than ETT

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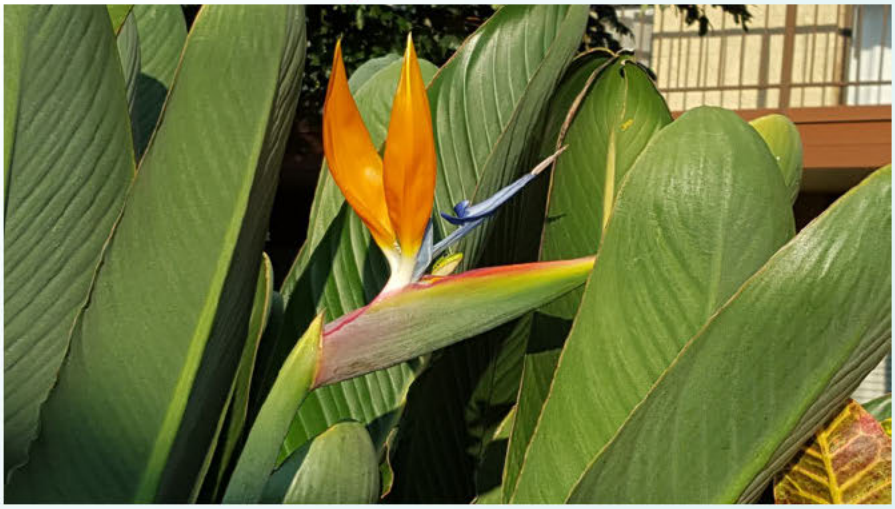
Questions?



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APPENDIX SLIDES

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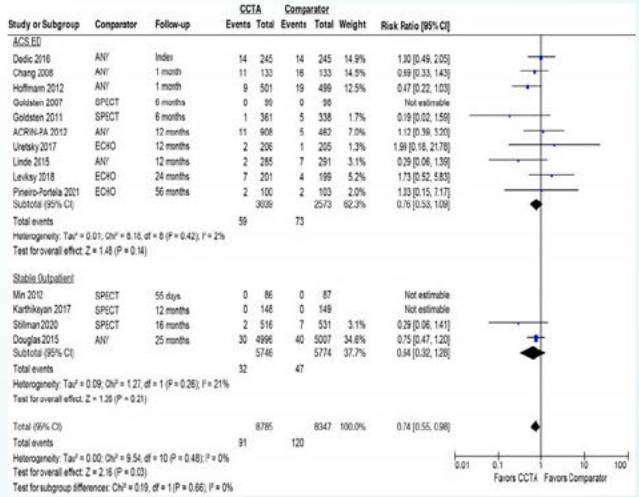
KQ 1 MI: CCTA vs. functional testing, excluding ETT



3 trials (N=667), no MI in either testing arm

Plot with Pooled results CCTA vs. Imaging only (11 RCTS, N= 16, 465)
RR 0.74 (0.55 to 0.98)

Exclude SCOT-HEART (13 RCTs, N= 17,515)
1.0 vs. 1.4 per 100
RR 0.75, (0.57 to 0.99)
RD 0.3, (0 to 0.5 per 100)

No clear difference in MI (SOE MODERATE)

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HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

Based on Legislative mandate: RCW 70.14.100(2).

The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. *Availability of evidence:*

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. *Sufficiency of the evidence:*

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Any major test-related AE		
Hospitalization for test-related complication		
Nephropathy		
Transient creatinine increase		
Chest pain, shortness of breath, or palpitations		
Stress-related symptoms and events; dipyridamole, adenosine-related events		
Arrythmias		
Radiation exposure		
Radiation exposure – Cumulative		
Incidental findings: "potentially serious" or requiring additional imaging *(CCTA arms only)*		
Contrast-related reaction, allergic reaction, skin rash/reaction, pruritis		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
MI		
All-cause death		
Cardiac death		
ICA referral		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Additional noninvasive testing (NIT)		
Revascularization		
Percutaneous coronary intervention (PCI)		
Hospitalization		
Subsequent ED visit		
Medication change		
ICA showing no obstructive CAD		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Race		
Gender		
Ethnicity		
Gender		
Diabetes (DM)		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

For cost outcomes/ cost-effectiveness:

Is there sufficient evidence that the technology is cost-effective for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not covered _____ Covered unconditionally _____ Covered under certain conditions

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.

Medicare Coverage

[see page 92 of the final report]

Payer (year)	Evidence Base	Covered	Not Covered
CMS (2021) National Coverage Determination (NCD) for Noninvasive Fractional Flow CT *No other NCD was determined to be appropriate at this time*	2 SRs of diagnostic accuracy 5 diagnostic accuracy studies 1 prospective observational cohort 3 retrospective observational studies 1 registry study	FDA-approved FFRct technology may be considered reasonable and necessary in the management of patients with symptomatic, stable ischemic heart disease (SIHD) when the CCTA analysis is completed and demonstrates one of the following criteria: 1. Left main disease with intermediate coronary stenosis (lumen diameter reduction of 30-50%); **OR** 2. Proximal and mid-left anterior descending (LAD) coronary artery disease with intermediate stenosis (lumen reduction 40-70%); OR Proximal and mid-left circumflex disease with intermediate coronary stenosis (lumen reduction 40-70%; (considered equivalent to two-vessel disease); OR 3. Proximal two- or three-vessel disease with intermediate coronary stenosis in at least two vessels; OR 4. Right coronary disease with intermediate (lumen reduction 40-70%) coronary stenosis This service should be performed in patients with stable coronary symptoms. It should not be performed until after the base study (CCTA) has been completed and interpreted. If higher grade stenoses (i.e., >70%) are present, this study is not medically necessary, as the patient should proceed to catheterization. Similarly, low-grade stenoses (< 30%) do not require additional confirmatory data. If more than two intermediate risk coronary	FFRct is not considered reasonable in the following clinical circumstance: 1. Severe obesity (BMI > 39 kg/m2) 2. Prior placement of prosthetic valves 3. Known severe aortic stenosis 4. Prior placement of grafts in coronary bypass surgery 5. Suspicion of acute coronary syndrome (where MI or unstable angina have not been ruled out) 6. Intracoronary metallic stent 7. Status post-heart transplantation 8. Recent MI (30 days or less) 9. Prior pacemaker or defibrillator lead placement 10. Newly diagnosed systolic heart failure, with no prior left heart catheterization 11. Left main coronary artery disease with Intermediated Coronary Stenosis (lumen reduction less than or equal to 30%) 12. Non-obstructing stenosis (<50% of all major epicardial vessels) on CTA or catherization in the past twelve

Payer (year)	Evidence Base	Covered	Not Covered
		lesions are identified, the clinical situation is considered high risk, and the patient should proceed directly to catheterization.	months, in the absence of a new symptom complex

Clinical Practice Guidelines

[see page 54 of the final report]

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons[71] 2012* *Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease*	CCTA in patients able **or** unable to exercise	5 meta-analyses, 3 controlled clinical trials	Because the presence of significant calcification often can preclude the accurate assessment of lesion severity or cause a false positive study, CCTA should not be performed in patients who have known extensive calcification or a high risk of CAD. CCTA is reasonable for patients with a low to intermediate pretest probability of IHD who are incapable of at least moderate physical functioning or have disabling comorbidity. CCTA might be reasonable for patients with an intermediate pretest probability of IHD who have at least moderate physical functioning or no disabling comorbidity.	• Class of recommendation: IIa • Level of evidence: B (Recommendation in favor of treatment or procedure being useful. Some conflicting evidence from single randomized trial or nonrandomized studies)
	CCTA in patients with inconclusive functional tests	1 prognostic study	CCTA is reasonable for patients with an intermediate	• Class of recommendation: IIa

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
			probability of CAD who has any of the following: a) Continued symptoms with prior normal test, or b) Inconclusive exercise or pharmacological stress, or c) Unable to undergo stress with MPI or Echo	• Level of evidence: C (Recommendation in favor of treatment or procedure being useful. Only divergent expert opinion, case studies, or standard of care available).
	Exercise with nuclear MPI or Echo in patients able to exercise	5 meta-analyses, 2 cost effectiveness studies, and 2 additional publications of unknown study design	Exercise stress with nuclear MPI or echocardiography is recommended for patients with an intermediate to high pretest probability of IHD who have an uninterpretable ECG and at least moderate physical functioning or no disabling comorbidity.	• Class of recommendation: I • Level of evidence: B
			Exercise stress with nuclear MPI or echocardiography is reasonable for patients with an intermediate to high pretest probability of obstructive IHD who have an interpretable ECG and at least moderate physical functioning or no disabling comorbidity.	• Class of recommendation: IIa • Level of evidence: B (Recommendation in favor of treatment or procedure being useful. Some conflicting evidence from single randomized trial or nonrandomized studies)

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
			Exercise stress with nuclear MPI is not recommended as an initial test in low-risk patients who have an interpretable ECG and at least moderate physical functioning or no disabling comorbidity.	• Class of recommendation: III (no benefit) • Level of evidence: C
	Pharmacological stress with nuclear MPI, Echo, or CMR in patients able to exercise	1 observational study, 2 economic evaluations	Pharmacological stress with nuclear MPI, echocardiography, or CMR is not recommended for patients who have an interpretable ECG and at least moderate physical functioning or no disabling comorbidity.	• Class of recommendation: III (no benefit) • Level of evidence: C
	Pharmacological stress with nuclear MPI or Echo in patients unable to exercise	5 meta-analyses, 1 observational study, 1 position statement, 1 economic evaluation	Pharmacological stress with nuclear MPI or echocardiography is recommended for patients with an intermediate to high pretest probability of IHD who are incapable of at least moderate physical.	• Class of recommendation: I • Level of evidence: B
	Pharmacological stress CMR in patients able to exercise	3 meta-analyses	Pharmacological stress with CMR can be useful for patients with an intermediate to high pretest probability of obstructive IHD who have an *un*interpretable ECG and at least moderate physical functioning or no disabling comorbidity.	• Class of recommendation: I • Level of evidence: B

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
	Pharmacological stress CMR in patients unable to exercise	3 meta-analyses, 1 RCT	Pharmacological stress CMR is reasonable for patients with an intermediate to high pretest probability of IHD who are incapable of at least moderate physical functioning or have disabling comorbidity.	• Class of recommendation: IIa • Level of evidence: B (Recommendation in favor of treatment or procedure being useful. Some conflicting evidence from single randomized trial or nonrandomized studies)
	Hybrid Imaging	N/A	This diagnostic imagining modality is discussed, but no specific recommendations for the use of hybrid imaging are included in this guideline.	N/A
The Task Force for the diagnosis and management of chronic coronary syndromes of the European Society of Cardiology (ESC)[133] 2019 *2019 ESC Guidelines for the diagnosis and management of chronic*	Stress echocardiography, stress CMR, SPECT, PET, or CCTA	5 RCTs, 1 meta-analysis, and 1 recommendation document	Stress echocardiography, stress CMR, SPECT, PET, or CCTA is recommended as the initial test to diagnose CAD in symptomatic patients in whom obstructive CAD cannot be excluded by clinical assessment alone.	• Class of recommendation: I • Level of evidence: B
	Selection of initial non-invasive diagnostic test.	None cited.	It is recommended that selection of the initial non-invasive diagnostic test is done based on the clinical likelihood of CAD and other patient characteristics that influence test	• Class of recommendation: I • Level of evidence: C

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
coronary syndromes			performance (e.g. characteristics determining ability to exercise, likelihood of good image quality, expected radiation exposure, and risks or contraindications), local expertise, and the availability of tests	
	CCTA	None cited.	CCTA should be considered as an alternative to invasive angiography if another non-invasive test is equivocal or non-diagnostic.	• Class of recommendation: IIa • Level of evidence: C
			CCTA is not recommended when extensive coronary calcification, irregular heart rate, significant obesity, inability to cooperate with breath-hold commands, or any other conditions make obtaining good image quality unlikely.	• Class of recommendation: III • Level of evidence: C
National Institute for Health and Care Excellence (NICE)[2] 2016 *Recent-onset chest pain of suspected cardiac origin: assessment and diagnosis*	CCTA	Specific references used to make this recommendation were not explicitly stated.	Offer 64-slice (or above) CCTA if: • clinical assessment indicates typical or atypical angina†, or • clinical assessment indicates non-anginal chest pain but 12-lead resting ECG has been done and indicates ST-T changes or Q waves. The committee's view is that CCTA should be considered the first choice diagnostic test	NR

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
			for all people assessed as having typical or atypical angina. However individual circumstances, including potential contraindications, should be considered when deciding the most appropriate strategy for diagnostic investigation.	
American College of Cardiology (ACC) and the American Heart Association (AHA)[14] 2014 *Guideline for the Management of Patients With Non–ST-Elevation Acute Coronary Syndromes*	ECG	1 position statement	In patients with chest pain or other symptoms suggestive of ACS, a 12-lead ECG should be performed and evaluated for ischemic changes within 10 minutes of the patient's arrival at an emergency facility.	• Level of evidence: C • Class of recommendation: I
	ECG	None cited.	If the initial ECG is not diagnostic but the patient remains symptomatic and there is a high clinical suspicion for ACS, serial ECGs (eg, 15- to 30-minute intervals during the first hour) should be performed to detect ischemic changes.	• Level of evidence: C • Class of recommendation: I
	Treadmill ECG, Stress MPI, Stress Echo	Treadmill ECG: 3 RCTs Stress MPI/Stress Echo: 1 comparative cohort, 1 prognostic study	It is reasonable for patients with possible ACS who have normal serial ECGs and cardiac troponins to have a treadmill ECG, stress myocardial perfusion imaging, or stress echocardiography before discharge or	• Treadmill ECG - Level of evidence: A - Class of recommendation: IIa • Stress MPI, stress echo - Level of evidence: B

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
			within 72 hours after discharge.	- Class of recommendation: IIa
	CCTA	3 RCTs	In patients with possible ACS and a normal ECG, normal cardiac troponins, and no history of CAD, it is reasonable to initially perform (without serial ECGs and troponins) coronary CT angiography to assess coronary artery anatomy	• Level of evidence: A • Class of recommendation: IIa
	MPI	1 RCT, 1 case series	In patients with possible ACS and a normal ECG, normal cardiac troponins, and no history of CAD, it is reasonable to initially perform (without serial ECGs and troponins) rest myocardial perfusion imaging with a technetium-99m radiopharmaceutical to exclude myocardial ischemia	• Level of evidence: B • Class of recommendation: IIa
	Stress testing	4 observational studies	Noninvasive stress testing is recommended in low and intermediate-risk patients who have been free of ischemia at rest or with low-level activity for a minimum of 12 to 24 hours	• Level of evidence: B • Class of recommendation: I
	Exercise stress test	3 observational studies	Stress testing with an imaging modality should be used in patients who are able to exercise but have ST changes on resting ECG that may interfere with interpretation.	• Level of evidence: B • Class of recommendation: I

	Imaging Modality or Diagnostic Consideration	Evidence Base	Recommendation	Strength of Recommendation
			In patients undergoing a low-level exercise test, an imaging modality can add prognostic information.	
	Pharmacological stress test	None cited.	Pharmacological stress testing with imaging is recommended when physical limitations preclude adequate exercise stress.	• Level of evidence: C • Class of recommendation: I

CCTA = coronary computed tomography, CMR = cardiac magnetic resonance, ECG = electrocardiogram, ECHO = echocardiography, IHD = ischemic heart disease, MPI = myocardial perfusion imaging, N/A = not applicable, NR = not reported, PET = positron emission tomography, RCT = randomized control trial, SPECT = single photon emission computed tomography.

* In 2014, an update to this guideline was published. However, none of the updates involved imagining modalities of interest to this review.

† According to NICE Guideline recommendation 1.3.3.1, assessing the typicality of chest pain should be done as follows:

· Presence of three of the features below is defined as typical angina.
· Presence of two of the three features below is defined as atypical angina.
· Presence of one or none of the features below is defined as non-anginal chest pain.

Anginal pain is:

· constricting discomfort in the front of the chest, or in the neck, shoulders, jaw, or arms
· precipitated by physical exertion
· relieved by rest or GTN within about 5 minutes.

Summary slides

Summary: CCTA vs. any functional test – Efficacy

Outcome	All patients	ED/similar setting	Stable outpatients
Key Question 1: Clinical outcomes			
MI	ϴ* Moderate SOE (14; N=21,661)	ϴ (10; N=5,977)	ϴ* (4; N=15,684)
All-cause death	ϴ **Moderate** SOE (11; N=18,935)	ϴ (7; N=4,001)	ϴ (4; N=14,934)
Cardiac death	Insufficient evidence	Insufficient evidence	Insufficient evidence
Key Question 2: Decision -making			
ICA	↑† Moderate SOE (19; N=22,335)	↑ (14; N=7,227)	ϴ† (4; N=15,107)
Any additional NIT	ϴ **Low** SOE (17; N=11,595)	ϴ (13; N=6,491)	ϴ (4; N=5,104)
Any revascularization	↑ Moderate SOE (19; N=23,124)	↑ (13; N=7,014)	↑ (19; N=16,110)
Hospitalization	Data not pooled	Index visit: Insufficient evidence ϴ High SOE 1-6.5 mos. (9; N=5,144) ≥12 mos. (6; N=3,624)	Any timepoint: ϴ Moderate SOE (4; N=14,810)
Subsequent ED visit	NR	ϴ High SOE 1-6.5 mos. (7; N=4,294) ≥12 mos. (5; N=2,855)	NR
Medication change	Insufficient evidence	Insufficient evidence	Insufficient evidence

Aggregate Analytics ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: other CCTA – Efficacy

Outcome	CCTA vs. ICA
KQ 1: Clinical outcomes	
MI	ϴ Moderate SOE (2; N=1,832)
All-cause death	ϴ Moderate SOE (2; N=1,832)
Cardiac death	Insufficient evidence
KQ 2: Decision making	
ICA	**Not showing obstructive CAD** ↓ Moderate SOE (2; N=1,832)
Any additional NIT	↑ Moderate SOE (1; N=1,503)
Any revascularization	↓ Moderate SOE (2; N=1,832)
Hospitalization	ϴ Moderate SOE (2; N=1,832)
Subsequent ED visit	NR
Medication change	NR

CCTA FFR

1 prospective cohort (N=584)
vs. planned noninvasive test (any) (N=204)
vs. planned ICA (N=380)

SOE: Insufficient for all clinical and decision-making outcomes

SOE: Low – cumulative radiation exposure

- ↑ with CCTA FFR vs. any NIT; no difference vs. ICA

Aggregate Analytics ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: CCTA vs. any functional test –Safety

Outcome	All patients
Any major test-related AE	ϴ Low SOE (0%; 3 RCTs, N=10,270)
Hospital admission for test-related complication	ϴ Low SOE (0% vs. 0.1%; 1 RCT, N=9,470)
Nephropathy	Insufficient evidence
Transient creatinine increase	ϴ Low SOE (0.2%–1% vs. 0%–0.4%; 2 RCTs, N=1,500)
Chest pain, shortness of breath, or palpitations	↓ Low SOE (0% –0.5% vs. 3%–16%; 2 RCTs, N=751)
Stress-related symptoms and events; dipyridamole, adenosinerelated events	ϴ Low SOE (0% vs. 0.1%–0.5%; 1 RCT, N=7,896)
Arrythmias (rapid AF, ventricular tachycardia, bradyarrhythmia)	Insufficient evidence
Radiation exposure – Index test (CCTA vs. SPECT)	↓ Low SOE (estimated range, 1.3–11.9 mSv; 5/6 RCTs, N=7,981)
Radiation exposure – Cumulative	↑ Low SOE (range of differences1.9–9.0 mSv; 9 RCTs; N=13,984)
Incidental findings: "potentially serious" or requiring additional imaging *(CCTA arms only)*	Common, Low SOE ("any": 28%–44%; "potentially serious, required follow-up": 5%–16%; 3 RCTs)
Extravasation of contrast *(CCTA arms only)*	Rare, Low SOE (stable OP: 0.3%0.4%; ED: 2%; 3 RCTs, N=6,911)
Mild contrast-related reaction, allergic reaction, skin rash/reaction, pruritis *(CCTA arms only)*	Rare, Low SOE (stable OP: 0.5%; ED: 1.2%; 5 RCTs, N=6,980)

Aggregate Analytics

ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: CCTA vs. ICA – Safety

Major AEs were rare, there were no differences between testing arms; RCTS may have been underpowered.

CCTA was associated with fewer minor procedural AEs (data not shown).

SOE LOW

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Major adverse events	≤48 hours, median 12 months	2 RCTs (N=1,832) Suspected CAD: 1 stable OP; 1 stable and acute, atypical chest pain	Imprecision (-2)	**Any complications prolonging hospital stay** No events in either test arm (1 RCT; N=327) **Major bleeding** Risk: 0 vs. 0.3 per 100 patients (1 RCT; N=1,503)	⊕⊕◯◯ LOW

Aggregate Analytics

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Summary: SPECT – Efficacy

Outcome	SPECT vs. Any functional test	SPECT vs. NICE guideline - directed care/clinical assessment	SPECT vs. ICA
Key Question 1: Clinical outcomes			
MI	Insufficient evidence	Insufficient evidence	Insufficient evidence
All-cause death	ϴ Low SOE (4; N=1,908)	Insufficient evidence	Insufficient evidence
Cardiac death	Insufficient evidence	Insufficient evidence	Insufficient evidence
Key Question 2: Decision -making			
ICA	ϴ* Low SOE (4; N=1,908)	↓ Low SOE (2; N=2,229)	NA
ICA showing no obstructive CAD	NR	↓ Low SOE (1; N=1,508; clinical)	NR
Unnecessary ICA	NR	↓ Low SOE (1; N=721; NICE)	NR
Any additional NIT	Insufficient evidence †	↓ Low SOE (1; N=1,508; clinical)	Insufficient evidence
Any revascularization	ϴ‡ Moderate SOE (4; N=1,908)	ϴ Low SOE (2; N=2,229)	↓ Low SOE (1; N=448)
Hospitalization	ϴ Low SOE (3; N=1,451)	↓ Low SOE (1; N=1,508; clinical)	ϴ Low SOE (1; N=448)
Subsequent ED visit	ϴ Low SOE (1; N=229)	NR	NR
Medication change	NR	NR	NR

Analytics

ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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Summary: SPECT – Safety

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Test-related AEs	Median 16 mos.	1 RCT (N=721)	Imprecision-2(2)	None following SPECT	⊕⊕◯◯ LOW
Radiation exposure	Index	1 RCT (N=722)	ROB (-1), imprecision-2(2)	Mean ionizing radiation: 14 mSv (SPECT) vs. NA (exercise ECG)	⊕◯◯◯ INSUFFICIENT
AEs related to regadenoson and dipyridamole	NR	1 retro cohort, 2 case series (N=380 patients, 604 AEs)	ROB (-1), imprecision-1(1)	Range 2% to 13% of patients Dipyridamole 5% to 37% of AEs Regadenoson 4% to 53% of AEs mostare likely expected, minor and transient	⊕⊕◯◯ LOW

Aggregate Analytics

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Summary: Stress Echocardiography – Efficacy

Outcome	Stress Echo vs. Exercise ECG	Stress Echo vs. Standard Care	Stress Echo vs. ICA
Key Question 1: Clinical outcomes			
MI	Insufficient evidence	Insufficient evidence	Insufficient evidence
All-cause and cardiac death	Insufficient evidence	Insufficient evidence	Insufficient evidence
Key Question 2: Decision -making			
ICA	**Stable outpatients:** ↓ Low SOE (1, N=385)	Insufficient evidence	NA
	ED/similar setting *: ϴ Low SOE (3; N=716)		
Any additional NIT	**Stable outpatients:** ↓ Low SOE (1, N=385)	Insufficient evidence	Insufficient evidence
	ED/similar setting †: Insufficient evidence		
Any revascularization	ϴ Moderate SOE (4; N=1,092)	Insufficient evidence	ϴ Low SOE (1, N=385)
Hospitalization	ϴ Moderate SOE (3; N=799)	Insufficient evidence	ϴ Low SOE (1, N=385)
Subsequent ED visit	NR	NR	NR
Medication change	NR	NR	NR

Aggregate Analytics

ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

Summary: Stress Echocardiography – Safety

	Follow-up	Studies	Downgrades	Conclusion Effect estimate	Quality (SOE)
Any complication	2 mos.	1 RCT (N=152)	ROB (-1), imprecision (-2)	None occurred (stress echo vs. exercise ECG)	⊕◯◯◯ INSUFFICIENT
Dobutamine - related AEs	NR	11 case series (N range, 86–2799)*	ROB (-2)	**Major AEs** (death, MI, UA, CVA, acute pulmonary edema): ≤0.1% across all outcomes	⊕⊕◯◯ LOW
				Arrythmia-related AEs • Any arrythmia and tachycardias: 0%–18% • Atrial fibrillation and bradycardia: ≤1%	
				Hypotension: 0.1%–12.5% **Hypertension:** 0%–7.5%	
				General, other (e.g., chest pain, nausea/vomiting, headache, dyspnea and tremors): 0% –31%	
Dipyridamole - and adenosine-related AEs	NR	4 case series (N range, 109–1429)	ROB (-2)	No **major AEs**; **minor AEs** are not uncommon and occurred with variable frequency and ranged from 0.2% (vomiting and nausea) to 43% (headache).	
Noniodinated contrast-related AEs		2 cohorts (N=6,750), 1 database study (N=3,071)	ROB (-2)	**Definite,** 1.3% (41/3071) and **Suspected,** 2.2% (68/3071) AEs [1 database study] **Allergic reaction:** <0.5%	

Some symptoms/events (e.g., dyspnea, flushing, etc.) are mild, transient and common expected reactions to stress agents and may not be considered AEs

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Summary: PET – Efficacy and Safety

Outcome	PET vs. SPECT
MI; all-cause death; cardiac death	Insufficient evidence
ICA; any revascularization; medication change	ϴ Low SOE (1; N=322)

- **KQ3 (Safety): No evidence**

Aggregate Analytics ϴ = no diff. b/w groups ↓ = decreased risk with CCTA ↑ = increased risk with CCTA

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KQ 5 Cost-effectiveness: All tests

- Firm conclusions regarding cost -effectiveness are not possible
- Results across studies were mixed
- CE/ICERs varied based on test sequencing, pre -test CAD probability, assumed accuracy of various tests

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Considerations

Pathology considerations

- Identification and degree of obstruction do not always correlate to patient symptoms, presence or degree of ischemia or functional impact
- Ischemia may be present in the absence of obstruction and would not be identified by anatomic testing
- Patient pre-test probability and other factors impact testing choice

Applicability

- There is substantial heterogeneity across studies regarding patients, determination of pre-test risk, equipment, testing and study methods
- All imaging tests require substantial expertise. Tests performed in the RCTs reflect this. The same level of expertise may not be available in all clinical settings. Similarly, state of the art equipment may not be available in all settings.
- Stress echo, SPECT are established modalities for CAD diagnosis; Fewer trials, reflect older technology and research methods; different research funding opportunities vs. CCTA
- All imaging modalities are clinically considered to be better than ETT

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