CORONARY COMPUTED TOMOGRAPHY ANGIOGRAPHY DERIVED CORONARY PLAQUE ANALYSIS

Definitions

1. QCA is an imaging **technique that provides objective and reproducible measurements of coronary artery dimensions.**

Concept:

Artificial intelligence (AI) based analysis software for identifying coronary lesions with ≥50% stenosis. This can be calculated but time consuming. The performance is comparable to comparison to blinded expert readers and quantitative coronary angiography.

Characterization of the study

2. What is the current "gold standard" for measurement/characterization of atherosclerosis?

3. Given the current available medical literature, is there sufficient evidence to validate the use of AI-QCT (Quantitative Coronary Analysis) in the repertoire of non-invasive imaging tests, to include in the standards of medical practice, and to include in the specialty Societal guidelines (e.g., guidelines for CAD evaluation, CP evaluation guidelines)? What evidence supports this and what limitations exist?

4. Scan preparation technique (use of beta blocker, use and dose of nitroglycerin) in CCTA/AI-QCT can alter the patient's clinical physiologic presentation at scan/test time (lower HR, lower BP, anti-ischemic effect, vasodilation with nitrate/lumen diameters) versus initial patient presentation with symptoms. AI-QCT appears to be beneficial for patient's atherosclerotic plaque burden and composition as important determinants that drive effective CAD treatment, however, other non-invasive diagnostic tests (stress-echo, stress MIBI, pharmacologic stress tests do not alter physiologic parameters for ischemia evaluation). The use of AI-QCT analysis software for plaque identification, morphology, genotype, percentage of vessel stenosis (at rest), data processing, and read expediency—potential use for CAD prevention and medical therapy. Please have SME comment on this concern.

5. Which medical profession specialties will perform and interpret these AI-QCT studies and what medical training and certification will be required (e.g., medical Fellowship trained, technician staff certification)?

6. What is the average number of views that an invasive cardiologist uses to determine coronary stenosis in clinical practice? Some articles compared AI-QCT to only 2 views of invasive coronary angiographic (ICA) views, could this effect the accurate stenosis severity when comparing AI-QCT versus ICA?

7. What is the quality of evidence on plaque burden and role in management of patients at risk for coronary artery disease/ acute coronary syndrome? Is there evidence to support that non-invasive imaging accurate for this evaluation?

Clinical applications

8. What clinical benefit can AI-QCT plaque analysis bring to clinical care? Does this technology change clinical management and how?

9. In the clinical decision pathways (CDPs) for patients presenting with chest pain and suspected ACS/CAD, coronary artery stenosis quantification and ischemia are significant determinants that guide disposition, conservative medical therapy, further non-invasive diagnostic imaging, or ICA with potential intervention. Please comment on the accuracy and indications of CCTA with AI-QCT versus other current imaging modalities regarding the following issues:

a. Coronary artery stenosis quantification

   i. Discuss the method and accuracy of CCTA with AI-QCT for stenosis quantification in patients with diffuse, non-focal, coronary artery disease such as diabetic or cardiac transplant patients.

b. Ischemia Evaluation

   i. Compare CCTA with AI-QCT versus other non-invasive imaging modalities (e.g., stress echocardiography, stress SPECT or PET MPI, CMR) which allows for detection of perfusion abnormalities, measures LVEF changes, identifies LV wall motion abnormalities, and identifies transient ischemic dilation as part of the ischemia evaluation.

   ii. The initial CCTA protocol uses B-blockers and nitroglycerin which are anti-ischemic medications. Will this not alter the accuracy for an ischemia evaluation?

   iii. The 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain recommends that “For intermediate-risk patients with acute chest pain and no known CAD eligible for diagnostic testing after a negative or inconclusive evaluation for ACS, CCTA is useful for exclusion of atherosclerotic plaque and obstructive CAD. For intermediate-risk patients with acute chest pain and no known CAD who are eligible for cardiac testing, either exercise ECG, stress echocardiography, stress PET/SPECT MPI, or stress CMR is useful for the diagnosis of myocardial ischemia”. The Guidelines further recommend that “For intermediate-risk patients with stable chest pain and no known CAD, CCTA is preferable in those <65 years of age and not on optimal preventive therapies; stress testing favored in those >65 years of age (with a higher likelihood of ischemia).” Will these recommendations remain?

10. What would be the role and indications for AI-QCT versus CCTA?

11. Can coronary CTA with AIQCT reduce the need for invasive angiography? If yes, which patients do you feel confident that you can relay on this data and not proceed with invasive angiograph. What evidence is there to support this and ensure the new technology does not miss lesions that would have been detected on invasive angiogram?

12. How does AI-QCT compare to invasive angiography with or without FFRCT? Are there situations where you need both measurements and if so which patients?

13. What specific patient population would CCTA with AI-QCT be utilized (e.g., risk stratification such as intermediate risk patients; established CAD; patients with symptomatic CP or angina-like symptoms; patients with cardiac devices, stents, or prosthetic valves; what degree of stenosis on a CCTA or prior invasive angiography study; or patients with recent MI, severe cardiomyopathy, or CHF); and for what indication (e.g., evaluation for plaques characteristics, stenosis severity, ischemia)

14. To further assess for the progression or regression of disease and effectiveness of therapy with AI-QCT-how often would repeat AI-QCT studies need to be performed?

15. Is there evidence to support non-invasive plaque analysis for the following patients? Would this be considered first line or adjunctive testing?

a. Elevated risk for a major cardiac event with ASCVD >7.5%
b. To further assess patients with significant non-calcified plaque(s) identified on a recent CCTA (disease staging)
c. To monitoring disease progression.
d. Assessment for CAD on recent CCTA that is of uncertain physiological significance? What is recent CCTA?
e. Assessment for CAD in patients with a family history of ischemic heart disease/ early MI? Would this be considered screening?

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