

IMAGE-CAD Pilot Study

Assessment of Patients with Suspected Coronary Artery Disease (CAD):

What is the best initial imaging strategy?



Cardiac Computed Tomographic Angiography (CCTA) vs Stress Echocardiography (SE) vs Single-Photon Emission Computed Tomography (SPECT)

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BACKGROUND

- Patients presenting with symptoms suspicious of Coronary Artery Disease (CAD) usually undergo tests to confirm or exclude CAD.
- There are major differences in costs and patient involvement between the tests. However, there is a limited evidence for what is gained by using a more invasive and costly test.
- According to National Institute for Clinical Excellence in the UK (NICE), the selection of imaging method should consider local expertise, availability and individual patient requirements. In reality the choice of test is dominated by cost to the health care purchaser and revenue to the healthcare provider. It is unknown weather higher costs for SPECT and CCTA are justified by better patient management and outcome. compared to SE.
- We hypothesize that SE is not inferior to SPECT and/or CCTA regarding patients outcome and downstream costs over one year.

OBJECTIVES

Primary Objective:

 The study primary objective is to conduct a health economic analysis by comparing the healthcare resource utilization and outcomes following randomization to one of the three different imaging strategies over one year in patients presenting with symptoms suggestive of CAD (including subsequent testing and vascularization).

Secondary Objectives:

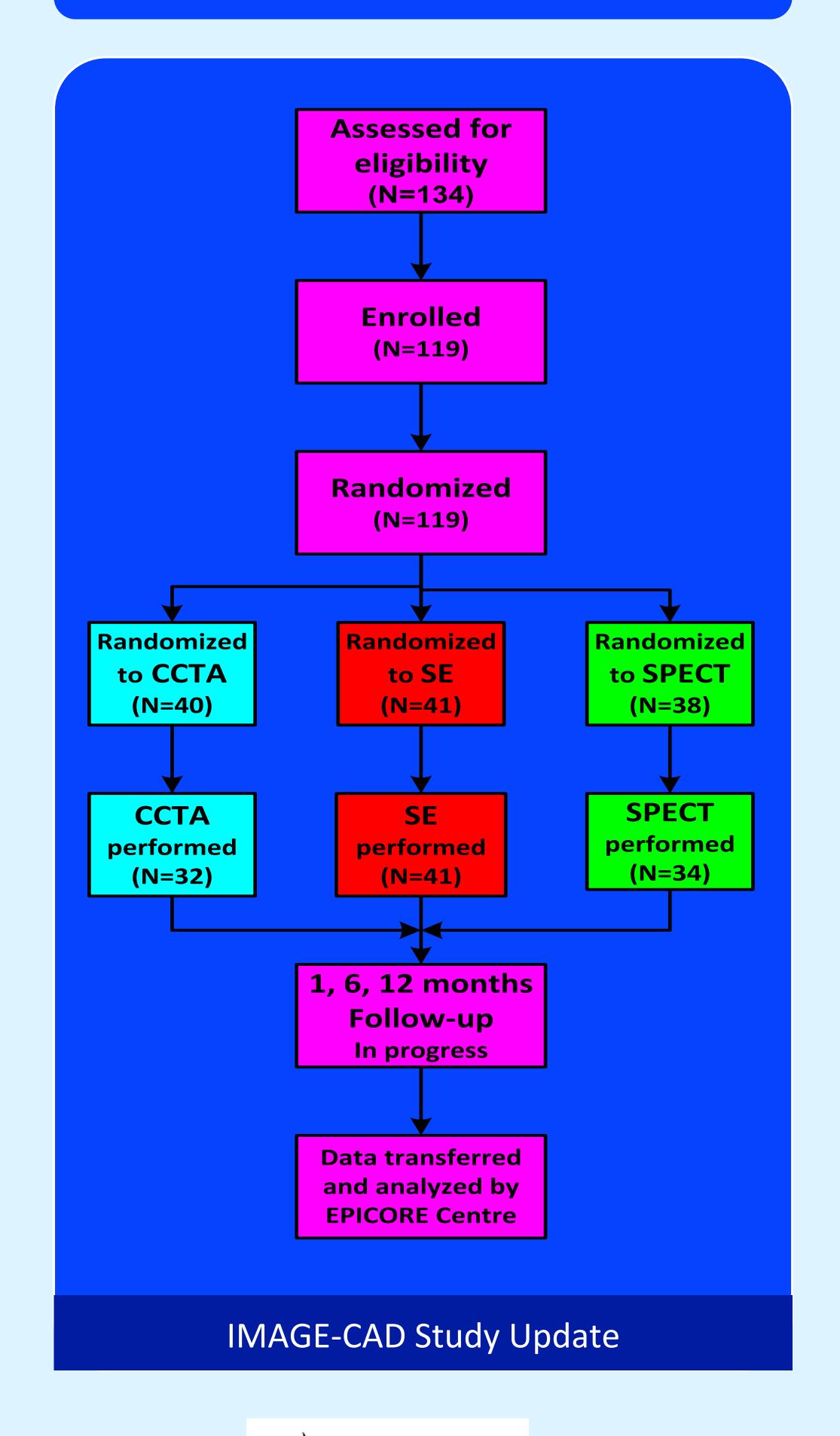
- To compare referral rates to Invasive Coronary Angiography
- To compare the ability of non-invasive tests to identify coronary lesions which warrant revascularization
- To compare radiation exposure from initial and subsequent cardiac imaging during 12 months follow-up period
- To compare 12 months clinical outcome (total and cardiac mortality, non-fatal MI, hospital admissions for angina
- To compare freedom from angina

METHODS To compare the cost-effectiveness and clinical utility of Study Aim three commonly used imaging strategies for diagnosis of CAD in patients presenting with Chest Pain Out/Inpatient Setting (Chest Pain Program Clinic, EASE Setting Clinic, Mazankowski Heart Institute and other Alberta Health Services medical facilities) Men and women without known CAD who present with symptoms suggestive of CAD and require diagnostic/ prognostic work up. (Low-intermediate pretest Screening& probability for CAD). Consent Eligible patients were screened by Principal Investigator Randomization Stress Intervention **SPECT** Echo **Baseline Assessment, Charts Review and** Telephone Interviews: 1, 6 and 12 months Primary **Cost-Effectiveness** Outcome **Additional Noninvasive Cardiac Tests Coronary Angiography and Coronary Interventions** Secondary **Angina Assessment and MACE** Outcome **Medical Costs** IMAGE-CAD Study Design

- The protocol and Informed Consent Forms were approved by University of Alberta HREB committee.
- This is a prospective cohort randomized pilot trial.
- All imaging tests in this trial are clinically indicated. The only change from clinical practice is the selection of the initial imaging test.
- The imaging results are presented to the referring physician who decides on further diagnostic and treatment.

STUDY UPDATE

- One hundred nineteen patients are recruited so far.
- The data is transferred to the EPICORE Centre database for analysis. Expected trial end is 2014.
- The recruitment rate is bellow the target.
- The majority of patients approached, have accepted to participate in the study.



Recruitment Challenges

- Study competes with other Mazankowski Alberta Heart Institute (MAHI) nuclear research studies.
- The physicians have to be constantly reminded about the study.
- Some patients have quick access to imaging outside hospital before their cardiologist appointment.
- Some physicians are hesitant to refer patients to IMAGE-CAD Study because their patients might be randomized to CCTA.
- The transition from Nurse Practitioner led Chest Pain Program Clinic (CPPC) to a busy Cardiologist - directed Chest Pain Clinic involves too many Health Care Providers that makes recruitment more challenging.

Points to improve recruitment for future studies

- Extend the screening to other Alberta health Services affiliated hospitals.
- Establish a central point of entry for all cardiology imaging tests referrals and have the referrals reviewed by a cardiologist before the patient undergo any cardiac imaging test.
- Keep randomization to functional tests

CONCLUSION

With IMAGE-CAD pilot trial we have established an infrastructure which allows us to plan and perform a multicenter trial and we are looking for partners in other provinces.

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