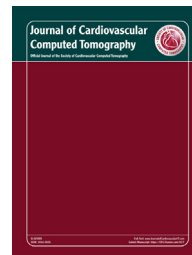




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Clinical Trial Design

Multicenter Evaluation of Coronary Dual-Source CT Angiography in Patients with Intermediate Risk of Coronary Artery Stenoses (MEDIC): Study design and rationale



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ABSTRACT

Background: The diagnostic performance of multidetector row CT to detect coronary artery stenosis has been evaluated in numerous single-center studies, with only limited data from large cohorts with low-to-intermediate likelihood of coronary disease and in multicenter trials. The Multicenter Evaluation of Coronary Dual-Source CT Angiography in Patients with Intermediate Risk of Coronary Artery Stenoses (MEDIC) trial determines the accuracy of dual-source CT (DSCT) to identify persons with at least 1 coronary artery stenosis among patients with low-to-intermediate pretest likelihood of disease.

Methods: The MEDIC trial was designed as a prospective, multicenter, international trial to evaluate the diagnostic performance of DSCT for the detection of coronary artery stenosis compared with invasive coronary angiography. The study includes 8 sites in Germany,

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India, Mexico, the United States, and Denmark. The study population comprises patients referred for a diagnostic coronary angiogram because of suspected coronary artery disease with an intermediate pretest likelihood as determined by sex, age, and symptoms. All evaluations are performed by blinded core laboratory readers.

Results: The primary outcome of the MEDIC trial is the accuracy of DSCT to identify the presence of coronary artery stenoses with a luminal diameter narrowing of 50% or more on a per-vessel basis. Secondary outcome parameters include per-patient and per-segment diagnostic accuracy for 50% stenoses and accuracy to identify stenoses of 70% or more. Furthermore, secondary outcome parameters include the influence of heart rate, Agatston score, body weight, body mass index, image quality, and diagnostic confidence on the accuracy to detect coronary artery stenoses >50% on a per-vessel basis.

Conclusion: The results of the MEDIC trial will assess the clinical utility of coronary CT angiography in the evaluation of patients with intermediate pretest likelihood of coronary artery disease.

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1. Introduction

Multidetector row CT (MDCT) allows visualization of the coronary arteries and detection of coronary artery stenoses. Two meta-analyses of trials performed by 64-slice CT reported sensitivities for detection of coronary artery stenoses in patients referred for a first diagnostic coronary angiogram to range from 73% to 99%, with specificities between 93% and 97%.^{1,2} Although numerous single-center trials have evaluated the performance of 64-slice coronary CT angiography (CTA), so far only 3 multicenter trials with cohort sizes from 230 to 360 patients have been published in peer-reviewed journals.^{3–5}

Dual-source CT (DSCT) allows imaging of the coronary arteries with better temporal resolution compared with 64-slice CT and may therefore be better suited to identify coronary artery stenoses in patients with elevated heart rates. In smaller trials performed without systematic use of β -blockers, sensitivities of 90% to 96% and specificities of 92% to 98% were reported for the detection of coronary artery stenoses on a per-segment level.^{6–10} The maximum number of patients included in these trials was 170, and no large trial that assesses the accuracy of DSCT for the detection of coronary artery stenoses has so far been performed.

According to an American Heart Association scientific statement, the use of coronary CTA is most likely considered clinically beneficial in patients who are at intermediate risk for having coronary artery stenoses: *Especially in the context of ruling out stenosis in patients with low to intermediate pretest likelihood of disease, CT coronary angiography may develop into a clinically useful tool. CT coronary angiography is reasonable for the assessment of obstructive disease in symptomatic patients (Class IIa, Level of Evidence: B, p. 1763).*¹¹ Another recent statement on noninvasive imaging of the coronary artery reads as follows: *The potential benefit of noninvasive coronary angiography is likely to be greatest and is reasonable for symptomatic patients who are at intermediate risk for coronary artery disease after initial risk stratification, including patients with equivocal stress-test results (Class IIa, level of evidence B, p. 598). Diagnostic accuracy favors coronary CTA over MRA [magnetic resonance angiography] for these patients (Class I, level of evidence B, p. 598).*¹²

A sufficiently large clinical trial is therefore needed to confirm the diagnostic accuracy of DSCT coronary

angiography in a multicenter setting and to confirm the clinical utility of coronary CTA, specifically in patients with intermediate pretest likelihood of coronary artery stenosis.

2. Methods

2.1. Overall study design and population

The Multicenter Evaluation of Coronary Dual-Source CT Angiography in Patients with Intermediate Risk of Coronary Artery Stenoses (MEDIC) trial is a prospective, multicenter, international trial to evaluate the diagnostic performance of DSCT for the detection of coronary artery stenoses. The study includes 8 sites in Germany, India, Mexico, the United States, and Denmark (Table 1). All sites participating in the trial are academic medical centers apart from the CARE Hospital in India. Patient inclusion and data acquisition were performed between May 2009 and March 2011. The study population

Table 1 – Participating sites.

Department	Institution	Country
Department of Cardiology	University of Erlangen	Germany
Department of Cardiology	University of Munich	Germany
Campus Grosshadern		
Department of Radiology	University of Texas	United States
	Southwestern Medical Center	
Department of Radiology	Massachusetts General Hospital	United States
	University of Munich	Germany
Department of Radiology	Campus Grosshadern	
Department of Cardiology	Vejle Hospital	Denmark
Department of Cardiology	CARE Hospital	India
Cardiac Imaging and Nuclear Cardiology	Cedars-Sinai Medical Center	United States
Department of Radiology	University of Erlangen	Germany
Facultad de Medicina	Universidad Nacional Autonoma de Mexico	Mexico
Cardiovascular Imaging and Nuclear Medicine Department	Instituto Nacional de Cardiologia "Ignacio Chavez"	Mexico

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