

EXPEDITED PUBLICATION

# Prevalence and Severity of Coronary Artery Disease and Adverse Events Among Symptomatic Patients With Coronary Artery Calcification Scores of Zero Undergoing Coronary Computed Tomography Angiography

Results From the CONFIRM (Coronary CT Angiography Evaluation for Clinical Outcomes: An International Multicenter) Registry

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## Objectives

The purpose of this study was to describe the prevalence and severity of coronary artery disease (CAD) in relation to prognosis in symptomatic patients without coronary artery calcification (CAC) undergoing coronary computed tomography angiography (CCTA).

## Background

The frequency and clinical relevance of CAD in patients without CAC are unclear.

## Methods

We identified 10,037 symptomatic patients without CAD who underwent concomitant CCTA and CAC scoring. CAD was assessed as <50%, ≥50%, and ≥70% stenosis. All-cause mortality and the composite end-point of mortality, myocardial infarction, or late coronary revascularization (≥90 days after CCTA) were assessed.

## Results

Mean age was 57 years, 56% were men, and 51% had a CAC score of 0. Among patients with a CAC score of 0, 84% had no CAD, 13% had nonobstructive stenosis, and 3.5% had ≥50% stenosis (1.4% had ≥70% stenosis) on CCTA. A CAC score >0 had a sensitivity, specificity, and negative and positive predictive values for stenosis ≥50% of 89%, 59%, 96%, and 29%, respectively. During a median of 2.1 years, there was no difference in mortality among patients with a CAC score of 0 irrespective of obstructive CAD. Among 8,907 patients with follow-up for the composite endpoint, 3.9% with a CAC score of 0 and ≥50% stenosis experienced an event (hazard ratio: 5.7; 95% confidence interval: 2.5 to 13.1;  $p < 0.001$ ) compared with 0.8% of patients with a CAC score of 0 and no obstructive CAD. Receiver-operator characteristic curve analysis demonstrated that the CAC score did not add incremental prognostic information compared with CAD extent on CCTA for the composite endpoint (CCTA area under the curve = 0.825; CAC + CCTA area under the curve = 0.826;  $p = 0.84$ ).

## Conclusions

In symptomatic patients with a CAC score of 0, obstructive CAD is possible and is associated with increased cardiovascular events. CAC scoring did not add incremental prognostic information to CCTA. (J Am Coll Cardiol 2011;58:2533–40) © 2011 by the American College of Cardiology Foundation

# Abbreviations and Acronyms

<b>CAC</b>	= coronary artery calcification
<b>CAD</b>	= coronary artery disease
<b>CCTA</b>	= coronary computed tomography angiography
<b>LR</b>	= likelihood ratio
<b>MI</b>	= myocardial infarction

Coronary artery calcium (CAC) scoring, using noncontrast computed tomography, is a clinically useful noninvasive estimate of coronary artery disease (CAD) burden (1). Among asymptomatic patients, the absence of measurable CAC is associated with very low adverse event rates (2), and CAC scoring is endorsed as a screening test in selected individuals (3) based on a convincing body of literature demonstrating that it

more precisely predicts adverse cardiovascular events compared with standard cardiovascular risk factor scoring (4). In symptomatic patients, absent CAC has been shown in several studies to have a high sensitivity and negative predictive value for excluding obstructive CAD (5), prompting a recent American College of Cardiology/American Heart Association consensus statement to endorse CAC as a “filter” for invasive angiography and/or hospital admission in patients with symptoms atypical for coronary ischemia (6). Specifically, it is recommended that CAC scoring may be used in a binary fashion (CAC present or absent) such that those without CAC may avoid further evaluation for obstructive CAD. Similarly,

recent guidelines have broadly endorsed the use of CAC scoring in selected symptomatic patients (7).

Several recent studies have questioned the utility of this approach, demonstrating relatively high rates of obstructive CAD in patients with CAC scores of 0, especially among patients at high pre-test risk of obstructive CAD (8–13). The prevalence of obstructive CAD among patients with CAC scores of 0 who are at lower clinical risk of obstructive CAD, such as those referred for coronary computed tomography angiography (CCTA), has not been well studied. Additionally, the prognostic importance of obstructive CAD among patients with a CAC score of 0 and the incremental prognostic value of CAC scoring performed at the time of CCTA are unclear. The aim of the current study was to assess the prevalence and extent of CAD and clinical outcomes among a large, international registry cohort of symptomatic patients without known coronary heart disease who were referred for CCTA and found to have no measurable CAC on pre-CCTA calcium scoring. The incremental prognostic value of CAC scoring at the time of CCTA was also explored.

## Methods

**Patients.** The CONFIRM (Coronary CT Angiography Evaluation for Clinical Outcomes: An International Multicenter) registry is an international, multicenter, observational registry collecting clinical, procedural, and follow-up data on patients who underwent  $\geq 64$ -detector row CCTA between 2005 and 2009 at 12 centers in 6 countries (Canada, Germany, Italy, Korea, Switzerland, and the United States). The rationale, design, site-specific patient characteristics, and follow-up durations have been described (14). Symptomatic patients who underwent concomitant CAC scoring and CCTA were included in the present analysis. Individuals with known CAD (previous myocardial infarction [MI] and/or coronary revascularization) were excluded. Institutional review board approval was obtained at each center.

As previously described (14), we prospectively collected information on the presence of cardiovascular risk factors in each individual. Chest pain was classified according to the methods of Diamond and Forrester (15). CAC was quantified according to the Agatston method (16).

Patient preparation, CCTA data acquisition, and clinical result reporting were done according to Society of Cardiovascular Computed Tomography guidelines (17). Image interpretation was performed in a uniform fashion at each site according to Society of Cardiovascular Computed Tomography guidelines (18) by highly experienced imagers who were level III equivalent and/or board certified in cardiovascular computed tomography. Coronary atherosclerotic lesions were quantified for lumen diameter stenosis by visual estimation and graded as none (0% luminal stenosis), mild (1% to 49%), moderate (50% to 69%), or severe

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