Journal of the American College of Cardiology
Vol. 46, No. 3, 2005
ISSN 0735-1097/05/$30.00
doi:10.1016/j.jacc.2005.05.056

Published by Elsevier Inc.

EXPRESS PUBLICATION

Diagnostic Accuracy of Noninvasive Coronary Angiography Using 64-Slice Spiral Computed Tomography

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OBJECTIVES The aim of our study was to evaluate the diagnostic accuracy of multislice computed tomography (MSCT) coronary angiography using a new 64-slice scanner.

BACKGROUND The new 64-slice MSCT scanner has improved spatial resolution of 0.4 mm and a faster rotation time (330 ms) compared to prior MSCT scanners.

METHODS We studied 70 consecutive patients undergoing elective invasive coronary angiography. Patients were excluded for atrial fibrillation, but not for high heart rate, coronary calcification, or obesity. All vessels were analyzed, including those <1.5 mm in diameter; MSCT lesions were analyzed quantitatively as well as by a qualitative scale and compared to quantitative coronary angiography (QCA). Results were also analyzed for significant coronary stenoses (over 50% luminal narrowing) by segment, by artery, and by patient.

RESULTS All scans showed diagnostic image quality. Of 1,065 segments, 935 (88%) could be evaluated, and 773 of 935 (83%) could be assessed quantitatively by both MSCT and QCA. The Spearman correlation coefficient between MSCT and QCA was 0.76 ($p < 0.0001$). Bland-Altman analysis demonstrated a mean difference in percent stenosis of 1.3 ± 14.2%. A total of 26% of patients had calcium scores above 400 Agatston U, 25% had heart rates >70 beats/min, and 50% were obese. Specificity, sensitivity, and positive and negative predictive values for the presence of significant stenoses were: by segment (n = 935), 86%, 95%, 66%, and 98%, respectively; by artery (n = 279), 91%, 92%, 80%, and 97%, respectively; by patient (n = 70), 95%, 90%, 93%, and 93%, respectively.

CONCLUSIONS Our results indicate high quantitative and qualitative diagnostic accuracy of 64-slice MSCT in comparison to QCA in a broad spectrum of patients. (J Am Coll Cardiol 2005;46:xxx)

Rapid advances in multislice computed tomography (MSCT) imaging technology have facilitated increasingly accurate noninvasive coronary artery imaging. Current generation 16-slice MSCT scanners have demonstrated highly accurate qualitative identification of significant coronary artery lesions (>50% stenosis) in vessels larger than 1.5 to 2 mm, with reported sensitivities and specificities ranging from 82% to 95% and 82% to 98%, respectively (1–6). A novel 64-slice MSCT scanner has recently been introduced that offers the potential for improved spatial and temporal resolution. The present study was designed to assess the accuracy of this 64-slice scanner in patients previously scheduled to undergo invasive selective coronary angiography for suspected coronary artery disease.

METHODS

Study population. In 70 consecutive patients scheduled to have elective invasive coronary angiography for suspected coronary artery disease, MSCT was performed within 30 days of catheterization. Exclusion criteria included irregular heart rate, patients at risk for iodinated contrast agents (congestive heart failure, dye allergy, or elevated serum creatinine >1.5 mg/dl), or contraindications to beta-blocking drugs. The human investigation committee approved the study protocol, and all patients gave informed consent.

Patient preparation. Patients not already on beta-blocking drugs received 100 mg of atenolol for heart rates over 65 beats/min, or 50 mg of atenolol for heart rates under 65 beats/min but over 50 beats/min, 1 h before MSCT imaging. Heart rate, electrocardiogram (ECG), and blood pressure were monitored, and additional intravenous metoprolol (5 to 30 mg) was administered to achieve a target heart rate <65 beats/min. However, no patient was excluded because of a heart rate above this target. Sublingual nitroglycerin 0.4 mg was given 1 min before image acquisition.

Scan protocol and image reconstruction. All patients were scanned on a 64-slice MSCT scanner (Sensation 64 Cardiac, Siemens Medical Systems, Forchheim, Germany). An initial nonenhanced ECG-gated scan was performed for calcium scoring. After an initial bolus-timing single-slice scan using 10 ml of contrast (Omnipaque, Amersham Health, Princeton, New Jersey, iodine content 350 mg/ml)

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Manuscript received April 6, 2005; revised manuscript received May 10, 2005, accepted May 17, 2005.

Abbreviations and Acronyms

CT	= computed tomography
ECG	= electrocardiogram
MSCT	= multislice computed tomography
QCA	= quantitative coronary angiography

followed by a 40-ml saline chaser, a contrast-enhanced scan was obtained using 100 ml of contrast injected through an antecubital vein at 5 ml/s followed by a 40-ml saline chaser. The scan parameters were: 32 × 0.6 mm collimation with dual focal spots per detector row; rotation time 330 ms; table feed 3.8 mm/rotation; tube voltage 120 mV; effective mA 750 to 850; volumetric computed tomography (CT) dose index 59 mGy and; no tube current modulation. Tube current modulation was not used to allow maximal flexibility in reconstruction intervals. Estimated effective radiation dose was 13 mSv for men and 18 mSv for women. Electrocardiographically gated datasets were reconstructed automatically at 65% of the R-R cycle length and 35% of the R-R cycle length to approximate end-systole and end-diastole, respectively. Additional reconstruction windows were constructed after examination of datasets if motion artifacts were present.

Noninvasive MSCT angiographic analyses. Calcium scores in Agatston U were analyzed using SYNGO software (Siemens Medical Systems; Forcheim, Germany); MSCT angiograms were analyzed on a three-dimensional workstation (Aquarius, TeraRecon, San Mateo, California). Scans were analyzed by consensus of two observers unaware of the clinical data and blinded to results of the invasive quantitative coronary angiography (QCA).

A previously described 15-segment American Heart Association model of the coronary tree was employed (7). Each lesion identified was examined using maximum intensity and multiplanar reconstruction techniques along multiple longitudinal axes and transversely. Lesions were classified by the maximal luminal diameter stenosis seen in any plane. Lesions with clear, well-defined borders were measured quantitatively. Quantitative CT angiographic analysis was performed on the most severe well-defined lesion in each segment, using a previously described digital caliper method (8). Lesions that could not be quantified to within 25% diameter stenosis because of hazy or irregular borders were classified by a qualitative severity scale: 0 = no stenosis, 1 = 1% to 25% stenosis, 2 = 26% to 50%, 3 = 51% to 75%, 4 = 75% to 99% stenosis, 5 = total occlusion. In the case of multiple lesions, in a given segment, the segment was classified by the worst lesion. In the case of multiple abnormal segments per artery, the vessel was classified by the worst segment. Patients were classified as positive for the presence of significant coronary artery disease if there was a stenosis >50% in any artery.

Patients were ranked by total calcium score, and segment and artery calcium was rated: 0 = not calcified; 1 = calcium present, no image impairment; 2 = calcium covering <50% of lumen; 3 = calcium covering >50% of lumen in all planes including in cross section.

Invasive angiographic analyses. Invasive coronary angiograms were evaluated by a single observer blinded to the MSCT results. Segmental disease was analyzed in each vessel using the same 15-segment model employed for MSCT analysis. Stenosis severity in each segment was classified according to the maximal luminal diameter stenosis present in each segment. Lesions were examined in orthogonal views, and stenosis severity determined using an automated edge-detection system (QuantCor.QCA, Pie Medical Systems, Masstricht, the Netherlands).

Comparative analyses. Quantitative *per-lesion analysis* compared the maximal percent diameter stenosis of the most severe lesion in each segment by each imaging modality. The accuracy of MSCT to detect significant disease (lesions >50%) was compared to invasive QCA according to the following analyses: 1) per-segment analysis, comparing each segment in every vessel; 2) per-artery analysis, examining the presence of significant lesions in each of the major coronary vessels (right coronary artery, left circumflex, left anterior descending, and left main); and 3) per-patient analysis, evaluating the presence of any significant lesion in a given patient. In determining MSCT lesion severity, quantitative values were always used if available.

Statistics. Quantitative lesion severity was compared between MSCT and QCA using Spearman correlation and Bland-Altman analysis, performed by plotting the stenosis difference between MSCT and QCA versus the average stenosis (9). For analysis of sensitivity, specificity, and positive and negative predicative accuracy, QCA lesion severity was used as the "gold standard." A two-tailed probability value of 0.05 was considered significant. SASS v.10 software (SAS, Cary, North Carolina) was used.

RESULTS

Clinical characteristics of the patient population. Seventy patients were enrolled during the period from September 2004 through February 2005. An additional 14 patients were screened but not enrolled due to: 1) arrhythmias found during examination before MSCT (atrial fibrillation, frequent extrasystoles, or sinus node dysfunction); or 2) historical exclusions that were elicited just before MSCT (dye allergy, bronchospasm). The clinical characteristics of the patients studied are summarized in Table 1. A significant proportion of patients had calcium scores above 400 Agatston U (26%), heart rates >70 beats/min (25%), or were obese (50%, body mass index ≥30 kg/m^2).

MSCT compared to QCA for quantification of lesion severity. Multislice CT was accurate in the quantitative assessment of lesion severity (Fig. 1). Overall, 935 of 1,065 (88%) could be analyzed either quantitatively or qualitatively. Of these, 773 of 935 (83%) segments could be quantitatively measured by both MSCT and QCA. Of

Table 1. Patient Characteristics

Age (yrs)	59 ± 11 (22–81)
Males	53/70 (73%)
Calcium scores* (Agatston units)	326 ± 472
0–100	35/70 (50%)
101–400	17/70 (24%)
401–1804	18/70 (26%)
Body mass index† (kg/m^2)	30 ± 5 (19–46)
<30	35/70 (50%)
30–38	29/70 (41%)
>38	6/70 (9%)
Heart rate, scanned (beats/min)	65 ± 10 (49–96)
<70	54/70 (67%)
70–80	10/70 (14%)
>80	6/70 (9%)

*Calcium score is in Agatston units. †Body mass index of ≥30 kg/m^2 denotes obesity, ≥38 kg/m^2 denotes extreme obesity.

these, 130 of 773 (17%) had stenoses. Comparing the maximal percent diameter luminal stenosis by MSCT versus QCA, the Spearman correlation coefficient between the two modalities was 0.76 ($p < 0.0001$) (Fig. 2A). Bland-Altman analysis demonstrated a mean difference in percent stenosis of 1.3 ± 14.2% (95% confidence interval 29.7% to −27.1%) (Fig. 2B). There was no significant correlation between stenosis difference and stenosis severity (Spearman correlation coefficient = −0.07, p = 0.59). A total of 90% (119 of 130) of the observations were within one qualitative stenosis score (25%) of the mean difference, and 94% (122 of 130) were within ±1.96 standard deviations.

MSCT compared to QCA for detection of significant stenoses. Overall, 935 of 1,065 (90%) segments could be interpreted, 773 of 935 (83%) quantitatively and 162 of 935 (17%) qualitatively only. On a per-segment basis, MSCT had a sensitivity of 86% (79 of 92) in detecting significant

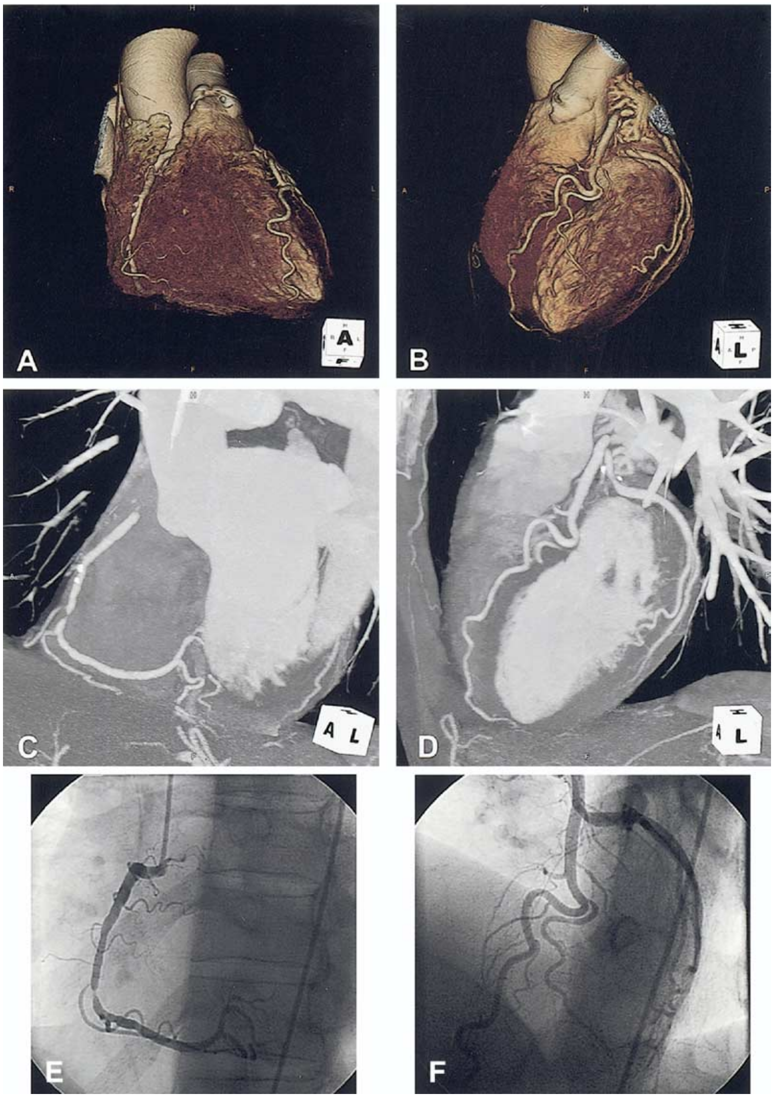

Figure 1. Visualization of soft and hard coronary atherosclerotic plaques by 64-slice multislice computed tomography (MSCT). **(A, B)** Volume rendering technique demonstrates stenosis of right coronary artery below the acute marginal branch **(A)**, as well as nodular coronary calcifications largely extrinsic to the right coronary lumen and **(B)** normal left coronary artery. **(C, D)** Maximum-intensity projection of the same arteries demonstrates severe soft plaque stenosis of the right coronary artery and superficial calcific plaque. **(E, F)** Invasive coronary angiography of the same arteries.

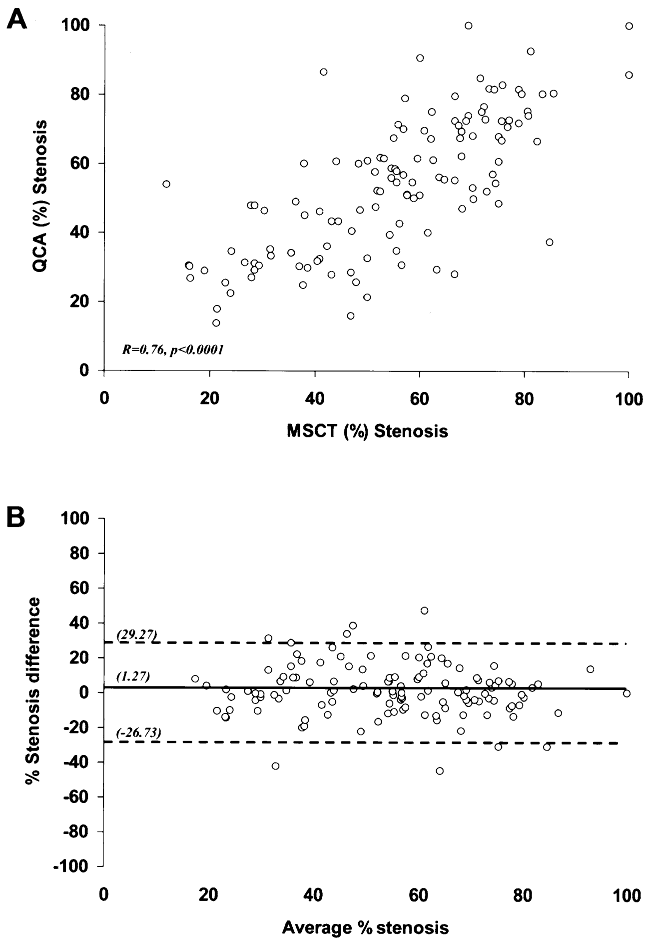

Figure 2. **(A)** Correlation between maximum percent diameter stenosis by quantitative analysis of multislice computed tomography (MSCT) compared with quantitative coronary angiography (QCA). The Spearman correlation showed an R value of 0.76, $p < 0.0001$, $n = 130$. **(B)** Bland-Altman analysis of the differences of percent diameter stenosis measured by MSCT and QCA compared to the average percent diameter stenosis by the two methods. The mean difference was $1.3 \pm 14.0\%$ **(central line)**. A total of 94% (122 of 130) of the values lie within 1.96 SDs of the mean **(outer lines)**. A total of 90% (119 of 130) of the observations were within one qualitative stenosis score (25%) of the mean difference. There was no significant correlation between stenosis difference and stenosis severity (Spearman correlation coefficient $= -0.07$, $p = 0.59$).

lesions on QCA, and a specificity of 95% (802 of 843) (Table 2). The positive predictive value was 66% (79 of 120), and negative predictive value was 98% (802 of 815).

A total of 279 of 280 (99%) arteries could be analyzed. On a per-artery basis, MSCT had a sensitivity of 91% (63 of 69) and a specificity of 92% (194 of 210). The positive predictive value was 80% (63 of 79), and negative predictive value was 97% (194 of 200).

All 70 patients could be analyzed for the presence of disease. Multislice CT correctly detected significant disease in 38 of 40 cases for an overall sensitivity per-patient of 95%. Multislice CT documented absence of significant disease in 27 of 30 patients for an overall specificity per-patient of 90%. The positive predictive value for any significant disease was 93% (38 of 41), and the negative predictive value was also 93% (27 of 29). Accurate determination of the presence or absence of significant coronary disease was made in 65 of 70 patients (93%).

Influence of calcium score on MSCT accuracy. We examined the accuracy of MSCT to detect a significant stenosis in a given patient according to calcium score (Agatston U). These results demonstrate that when calcium score was low (0 to 100 U), sensitivity was 94%, specificity was 95%, positive predictive value was 94%, and negative predictive value was 95% (Table 3). Multislice CT remained highly accurate in the presence of moderate calcification, but extreme calcification (401 to 1,804 U) reduced specificity (67%, 2 of 3) and negative predictive value (67%, 2 of 3), although the number of patients in these categories is too low to be conclusive.

Influence of obesity on MSCT accuracy. We examined the accuracy of MSCT to detect a significant stenosis in a given patient according to body mass index category (10). These results demonstrate that when body mass index was normal (<25 kg/m^2), sensitivity, specificity, and positive and negative predictive values were all 100% (Table 4). Multislice CT remained highly accurate in the presence of overweight, but obesity (body mass index ≥ 30 kg/m^2) reduced sensitivity to 90%, specificity to 86%, positive predictive value to 91%, and negative predictive value to 86%.

Influence of heart rate on MSCT accuracy. We examined the accuracy of MSCT to detect a significant stenosis in a given patient according to heart rate (Table 5). These results demonstrate that when heart rate was <70 beats/min, sensitivity was 97%, specificity was 95%, positive predictive accuracy was 97%, and negative predictive accuracy was 95%. There was a significant deterioration of accuracy at rates of 70 beats/min or higher, with sensitivity declining to 88%, specificity to 71%, positive predictive accuracy to 78%, and negative predictive accuracy to 83%.

Table 2. Diagnostic Accuracy of Coronary MSCT Compared to QCA for Detection of Lesions >50% in Patients

	Sensitivity	Specificity	PPV	NPV
Patients (n = 70)	38/40 (95%)	27/30 (90%)	38/41 (93%)	27/29 (93%)
Arteries (n = 279)	63/69 (91%)	194/210 (92%)	63/79 (80%)	194/200 (97%)
Segments (n = 935)	79/92 (86%)	802/843 (95%)	79/120 (66%)	802/815 (98%)

Values are n (%).
MSCT = multislice computed tomography; NPV = negative predictive value; PPV = positive predictive value; QCA = quantitative coronary angiography.

Table 3. The Effect of Coronary Calcification on Diagnostic Accuracy of Coronary MSCT Compared to QCA

	Sensitivity	Specificity	PPV	NPV
Patients' calcium score*				
0–100 (n = 35)	15/16 (94%)	18/19 (95%)	15/16 (94%)	18/19 (95%)
101–400 (n = 17)	9/9 (100%)	7/8 (88%)	9/10 (90%)	7/7 (100%)
401–1,804 (n = 18)	14/15 (93%)	2/3 (67%)	14/15 (93%)	2/3 (67%)
Calcium rating: arteries				
None	22/25 (88%)	144/147 (98%)	144/147 (98%)	144/147 (98%)
Mild	10/11 (91%)	21/25 (84%)	10/14 (71%)	21/22 (95%)
Moderate	10/11 (91%)	16/19 (84%)	10/13 (77%)	16/17 (94%)
Severe	21/22 (95%)	12/18 (67%)	21/27 (78%)	12/13 (92%)
Calcium rating: segments				
None	27/35 (77%)	660/674 (98%)	27/41 (66%)	660/668 (99%)
Mild	13/15 (87%)	69/74 (93%)	13/18 (72%)	69/71 (97%)
Moderate	11/12 (92%)	30/36 (83%)	11/17 (65%)	30/31 (97%)
Severe	28/30 (93%)	42/58 (72%)	28/44 (64%)	42/44 (95%)

*Calcium scores are in Agatston units. Values are n (%).
Abbreviations as in Table 2.

DISCUSSION

Observations from this study demonstrate that this 64-slice MSCT scanner consistently provides high-quality noninvasive coronary arteriograms that accurately delineate the presence or absence of significant lesions within the entire coronary tree in a broad spectrum of patients, including those with marked coronary calcification, relatively high heart rates, and obesity.

The present findings are consistent with and extend those of prior MSCT coronary angiographic studies employing 16-slice scanners. In aggregate, these studies document that noninvasive coronary MSCT imaging can accurately determine the presence or absence of significant coronary lesions. However, prior studies, with one exception (4), employed qualitative analyses only. Furthermore, in contrast to the present study, these prior studies excluded many "real-world" patients because of high heart rates, coronary calcification, or obesity, in addition to excluding all vessels <1.5 mm in diameter.

In comparison to 16-slice MSCT scanners, the present 64-slice scanner has increased slices per gantry rotation (64 vs. 16) and faster gantry speed (330 ms/rotation vs. 375), which translate into superior spatial resolution (0.4 vs. 0.75 mm) and temporal resolution (165 vs. 188 ms). The reduction in voxel size makes the distinction between hypointense soft plaque and blood pool contrast more evident. Consequently, this study was able to provide quantitative comparison of percent diameter stenosis of individual lesions by MSCT with invasive QCA, showing a mean difference of 1.3% and a relatively small standard deviation of 14.2%. This implies that 64-slice MSCT can predict QCA results within one qualitative stenosis grade (25%) with about 90% probability, an estimate that may be of use in designing future clinical trials.

Smaller voxel size also reduces partial volume effects, minimizing the degree of calcium blooming and beam-hardening artifacts. Partial volume effects are due to averaging of different densities within a single voxel. Calcium deposits are metal density and thus overwhelm the density of other tissues in the same voxel. Beam hardening is due to the attenuation of low-energy X-ray by very dense structures such as calcium. A higher energy beam, causing a darker appearance that can be mistaken for plaque, therefore penetrates adjacent pixels. All these effects can be modified, but not eliminated, by the smaller voxel size produced by the 64-slice scanner. The efficacy of this scanner in ameliorating imaging difficulties is shown in an overall sensitivity of 95% and specificity of 90% for the detection of angiographically significant stenoses even in the presence of high coronary calcium scores (26% of patients over 400 Agatston U, range up to 1,804 U), increased heart rates (23% over 70 beats/min, range up to 96 beats/min), or obesity (50% with body mass index of $\geq$30 kg/m^2, range up to 46 kg/m^2). Only 12% of segments and only one artery could not be

Table 4. The Effect of Obesity on Diagnostic Accuracy of Coronary MSCT Compared to QCA

Body Mass Index	Sensitivity	Specificity	PPV	NPV
Normal (<25 kg/m^2) (n = 10)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
Overweight (25–29.9 kg/m^2) (n = 25)	14/14 (100%)	10/11 (91%)	14/15 (93%)	10/10 (100%)
Obese ($\geq$30 kg/m^2) (n = 35)	19/21 (90%)	12/14 (86%)	19/21 (91%)	12/14 (86%)

Values are n (%). Weight classification as per Kalendar et al. (11).
Abbreviations as in Table 2.

Table 5. The Effect of Heart Rate on Diagnostic Accuracy of Coronary MSCT Compared to QCA

Heart Rate	Sensitivity	Specificity	PPV	NPV
Under 70 (beats/min)	31/32 (97%)	21/22 (95%)	31/32 (97%)	21/22 (95%)
71–85 (beats/min)	7/8 (88%)	5/7 (71%)	7/9 (78%)	5/6 (83%)
Over 85 (beats/min)	0/0	1/1 (100%)	0/0	1/1 (100%)

Values are n (%).
Abbreviations as in Table 2.

interpreted, and no patient was excluded because of poor image quality.

In spite of this high overall accuracy, our subset analysis confirms that patients with calcium scores over 400, obesity (body mass index >30 kg/m^2), and heart rates over 70 beats/min remain a challenge to diagnose.

Study limitations. Because all patients were referred for catheterization, there was a high incidence of true disease (54%) in our patients, tending to increase sensitivity. In the most calcified segments, the positive predictive value was relatively poor at 64% and might have been even lower if the incidence of true disease in these segments had not been extremely high (78%). On the other hand, the very high incidence of disease in these segments makes it more impressive that the negative predictive accuracy was 95%. This study excluded patients with suspected acute coronary syndromes, and further research is needed to establish the degree of accuracy in that setting. We must emphasize the primary importance of the per-patient results in interpreting this study, because we did not analyze the possible effects of within-patient correlations on per-artery and per-segment results. Quantitative analysis of lesion severity was also limited by the fact that 17% of lesions could not be analyzed quantitatively. The present study was also limited to small numbers of patients in a single center. Limitations of coronary MSCT with 64-slice scanners include radiation exposure (10), the use of contrast, and the need for beta-blocker therapy to reduce heart rate.

Clinical implications. The present results may have important clinical implications. The very high negative predictive value observed in this study (98% by segment, 97% by artery, and 93% by patient) suggests that coronary CT angiography with high-resolution scanners could be a suitable means for rapid triage of patients presenting to emergency centers with chest pain, and for evaluation of patients with equivocal stress test results who might otherwise require invasive angiography. However, future studies are necessary to determine whether present-generation MSCT scanners have sufficient resolution to delineate complex and unstable lesions.

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