**Symposium: Clinical Research**

**64-row multi-detector computed tomography coronary image from a center with early experience: first illustration of learning curve**

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**Background and objectives** The recent joint ACCF/AHA clinical competence statement on cardiac imaging with multi-detector computed tomography recommended a minimum of 6 months training and 300 contrast examinations, of which the candidate must be directly involved in at least 100 studies. Whether this is adequate to become proficient in interpretation of coronary computed tomography angiography (CTA) is not known. The aim of our study was to plot the 'learning curve' for CTA assessment of haemodynamically significant coronary stenosis in a center with 1 year's experience using a 64-row scanner. Methods A total of 778 patients underwent contrast-enhanced CTA between January and December 2005. Out of these patients, 301 patients also underwent contrast-enhanced conventional coronary angiography (CCA). These patients were divided into 4 groups according to the time the examination was underwent. Group Q1: first quarter of the year (n=20), Group Q2: second quarter (n=128), Group Q3: third quarter (n=134), and Group Q4: fourth quarter (n=19). For Group Q4 patients we used a 'test-bolus' protocol instead of 'bolus-tracking' for contrast-enhancement. Results The sensitivity, specificity, positive, and negative predictive values were Q1 - 64%, 89%, 49% and 94%, respectively; Q2 - 79%, 96%, 74% and 97%, respectively; Q3 - 78%, 96%, 74%, 97%, respectively, and Q4 - 100% for all. Conclusions In a center with formal training and high caseload, our accuracy in CTA analysis reached a plateau after 6 months experience. Test-bolus protocols produce better image quality and can improve accuracy. New centers embarking on CTA will need to overcome an initial 6-month learning curve depending upon the caseload during which time they should consider correlation with CCA. (J Geriatr Cardiol 2006; 3(1):29-34 )

**Key Words** computed tomography; training; angiography; coronary artery disease

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**Introduction**

In a recent joint clinical competence statement on computed tomography-assisted cardiac imaging by the American College of Cardiology Foundation and American Heart Association, several recommendations and guidelines were agreed upon in order to assist in the assessment of physicians' expertise in the ability to apply and interpret cardiovascular computed tomography. This report addresses a growing concern in the medical field about the rapid expansion of use of emerging unproven technology for coronary imaging. The 'gold standard' in coronary imaging remains invasive conventional coronary angiography (CCA). This is now being challenged by the less invasive multidetector computed tomography-assisted angiography (CTA), with apparently high accuracy rates of detection in comparison to CCA. Many of these reports were generated by centers with over 5 years' experience. As technology improved, the same operators, utilizing 16-row and 64-row scanners, reported dramatically improved rates of accuracy.

This has captured the attention of many diagnostic and imaging centers around the world. There is some concern that centers with little or no experience are quoting rates of accuracy from established centers when performing these scans, thinking that improved scan technology could compensate for their inexperience when reporting CTA images, and that CTA could replace CCA as the gold-standard for coronary imaging. Exactly how long it takes to become confident in interpreting CTA is unknown. The purpose of our study was to plot the 'learning curve' period in our center during our first year of operations, in terms of CTA interpretation.
Methods

Study population
Our hospital installed a 64-row MDCT (64 Sensation cardiac, Siemens, Germany) in early January 2005, and initiated operations on January 14, 2005. Between January 15 and December 15 of that year, 778 patients underwent coronary CTA at our center. Coronary imaging by CTA and CCA (less than 3 months apart) were available for comparison for 301 patients. These patients were grouped according to the quarter of the year the CTA was performed. Hence, there were 20 patients in the first quarter (Q1, January to March), 128 patients in the 2nd quarter (Q2, April to June), 134 patients in the 3rd quarter (Q3, July to September), and 19 patients in the 4th quarter (Q4, October to December, during this period only patients using test bolus were included). Indications for CTA include patients with known or suspected coronary artery disease requiring coronary imaging. Exclusion criteria for CTA included previous coronary bypass graft surgery, atrial fibrillation and other irregular or tachycardic heart rhythm, known allergy to iodine contrast media or beta-blockers, inability to hold breath for at least 15 s, and documented renal insufficiency (serum creatinine >140 μmol/L). The study protocol was approved by the local institutional ethics committee, and all patients gave written informed consent to undergo both CTA and CCA.

Multi-detector CT scan
Patient preparation In the absence of contraindications, all patients with a resting heart rate of >60 bpm received 100 mg Tenormin® (Astra Zeneca, UK) the night before the scan, and another 100 mg 1-2 hours before the scan. If the prescan heart rate remained >70 bpm, an additional 5 mg dose of intravenous Betaloc® (Astra Zeneca, UK) was given before the scan to further reduce the heart rate. All patients also received 2.5 mg sublingual Isokct® (Sifa, Ireland) immediately prior to the scan.

CTA scan protocol: bolus-tracking versus test bolus
From January to mid-October, we employed the ‘bolus-tracking’ method for contrast-enhancement, as described in other reports.11,12 A fully-automated real-time anatomy-based dose regulation (CAREDose 4D) was utilized for all patients. 80-90 ml of contrast Omnipaque 350 (GE Healthcare, UK) was continuously injected into a large cubital vein at a rate of 4 ml/s, followed by a saline injection of 50 ml at a flow rate of 4 ml/s. As soon as the signal density in the ascending aorta reached a predefined threshold of 100 Hounsfield units (HU), the patient was instructed to maintain an end-inspiratory breath hold during which the CT volume data set and ECG trace were acquired. All CT scans were completed within a 12 sec breath-hold (mean 9 ±1.1 sec). Since November, we adopted a ‘test-bolus’ method whereby 10 ml of contrast were infused initially at 5 ml/s, and the period taken from the start of the infusion to maximum contrast-enhancement at the aortic root is calculated.13,14 This period was added to the time needed to instruct the patient to hold his breath, plus a further two sec. The total time is the ‘delay’ from the start of infusion to the start of scan. This method used 60-70 ml of contrast. CT gantry rotation time was 330 msec. Tube voltage and effective tube current-time product were 120 kV and 900 mAsecff..

CTA image reconstruction and post-processing
For axial image reconstruction an effective row thickness of 0.75 mm and a reconstruction increment of 0.5 mm were applied, utilizing an ECG-gated half-scan reconstruction algorithm. Initial data set reconstruction was performed at 65% of the cardiac cycle. If motion artifacts were present, further reconstructions were done at different positions within the cardiac cycle. All data sets were reconstructed with a 5122 reconstruction matrix and B25f convolution kernel resulting in a spatial resolution of equal to or better than 0.4×0.4×0.4 mm3.15,17 If the vessel segment contained heavy calcification, additional reconstructions were performed using a row thickness of 0.6 mm with a reconstruction increment of 0.4 mm and B46f++ kernel. Stented segments were excluded from analysis in this study.

Training and reporting
The CTA images were analyzed by 4 cardiologists using a combination of axial images, multiplanar reconstructions, and thin-slab maximum intensity projections (3.0-9.0 mm). 2 cardiologists had attended a 4-day workshop in Erlangen, Germany, one in Rotterdam, Netherlands and the fourth in Washington, USA. Further training was given by the Siemens product applications specialist in the initial 2 months following installation. All CTA-CCA reporting and correlations were performed at the end of every quarter. Cardiologists interpreting the CTA were blinded to the findings of the corresponding CCA, and vice versa. CTA used for training purposes was excluded from analysis. 16 segments were identified, based on established AHA criteria, that comprised the right coronary artery and distal branches (5 segments), left main stem (1), left anterior descending artery and branches (5), and circumflex artery and branches (5). Diseased segments were graded as 1 = mild or no stenosis, 2 = greater than 50% stenosis (percentage luminal diameter narrowing compared to pre- and post-stenotic vessel lumen) by visual estimation. Stenoses ≤50% were regarded as significant. Segments that were absent or too small (less than 1.5 mm diameter), or heavily calcified or stented were scored 0 = non-evaluable.

Conventional coronary angiography
Conventional coronary angiography (CCA) was performed with a bi-plane digital fluoroscopy (Infinix, Toshiba Corp., Japan) and Omnipaque 350 (GE Healthcare, UK) contrast agent. A minimum of 6 orthogonal views were obtained. The CCA was interpreted by 2 cardiologists with at least 10 years, intervention experience, each blinded to the CTA findings (Fig. 1).

Statistical analysis
All data were stored on Microsoft Access and transferred to SPSS 11.5. The specificity, sensitivity, positive predictive value (PPV), and negative predictive value (NPV) of detecting significant coronary stenoses on CTA was compared to
CCA by cross-tabulation. Analyses were performed on the left main stem and 3 segments of the left anterior descending artery, circumflex artery, and the right coronary artery. Further analyses based upon 16-segment classification were performed for the periods of Q2 to Q4. For baseline characteristics and comparisons between groups of patients, continuous variables were expressed as mean ± SED and compared using ANOVA, while non-parametric variables were expressed as median (interquartile range) and compared using Kruskal-Wallis test. Discrete variables were expressed in absolute counts and percentages and compared by Chi square.

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Results

Baseline characteristics
The baseline characteristics of patients were shown in Table 1. There were no differences in patient age and heart rate among the four groups. Mean calcium score was highest in Q2 and similar for other groups. Mean contrast volume used was lowest in Q4 with the new protocol.

Calcium scoring was based on the modified Agaston method.

Accuracy on 10-segment analysis
In Q1, assessments and correlations were performed on the 10 main vessel segments only. All segments were evaluated. There were a total of 25 diseased segments. The sensitivity obtained was 64%, specificity 89%, Positive predictive value (PPV) 48.5%, and Negative predictive value (NPV) 93.8%. In Q2, 89% segment can be evaluated, 11% of the segments were stented previously, or heavily calcified and excluded from further evaluation. 152 diseased segments were identified on CCA. The sensitivity, specificity, PPV, and NPV were 78.7%, 95.9%, 73.6%, and 97.3%, respectively. In Q3, 91.3% of the segments were evaluated with 178 diseased segments. The corresponding results were 78.2%, 95.7%, 73.9%, and 97.4%. In Q4 after change of protocol, 98.5% of segments were evaluable. The accuracy rates were 100% for sensitivity, specificity, PPV, and NPV.

Accuracy on 16 segment analysis
No data of 16 segments analysis were available for Q1 of CTA performed in February and March 2005. From the 2nd quarter, analysis of the complete coronary tree was available. In Q2, 87% were evaluable, the remainder being stented previously (main vessel segments), absent or small (mainly in the branches), or due to heavy calcification. 198 diseased segments were identified on CCA. The sensitivity, specificity, PPV, and NPV were 69.5%, 96.6%, 69.8%, and 97.0%. In Q3, 83% of the segments were evaluable of which there were 236 diseased segments. The corresponding results were 66.1%, 96.5%, 71%, and 96.6%. In Q4 after change of protocol, 95% of segments were evaluable (exclusions were mainly for absent branches).
Table 1. A comparison of 301 patients who underwent computed-tomographic and conventional coronary angiography in a center with early experience in 2005, subdivided by quarterly year

<table>
<thead>
<tr>
<th></th>
<th>Group Q1</th>
<th>Group Q2</th>
<th>Group Q3</th>
<th>Group Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>20</td>
<td>128</td>
<td>134</td>
<td>19</td>
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<td>Mean age (yr)</td>
<td>53 ± 10</td>
<td>56 ± 10</td>
<td>55 ± 9</td>
<td>54 ± 10</td>
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<td>Heart rate (bpm)</td>
<td>63 ± 10</td>
<td>62 ± 10</td>
<td>62 ± 9</td>
<td>60 ± 4</td>
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<tr>
<td>Contrast volume (ml)</td>
<td>87 ± 12</td>
<td>85 ± 12</td>
<td>85 ± 7</td>
<td>65 ± 3</td>
</tr>
<tr>
<td>Calcium scoring (HU)</td>
<td>174 ± 288</td>
<td>340 ± 602</td>
<td>162 ± 250</td>
<td>158 ± 124</td>
</tr>
</tbody>
</table>

Fig. 2. Accuracy of coronary disease detection in main vessel segments by computed tomography-assisted angiography compared to conventional coronary angiography in a center with 1 year’s experience, subdivided by quarterly year.

Fig. 3. Accuracy of coronary disease detection in a 16-segment coronary tree by computed tomography-assisted angiography compared to conventional coronary angiography in a center with 1 year’s experience, subdivided by quarterly year.
The sensitivity, specificity, PPV, and NPV were 93.8%, 100%, 100%, and 99.4%, respectively. Lesions missed on CTA belonged to distal branches.

Discussion

Our quarterly analyses of CTA accuracy compared to CCA are in line with the minimum recommendations of the ACCF/AHA clinical competence statement. However, proficiency in computed tomography-assisted cardiac imaging is far more than just the ability to interpret images accurately. Therefore, in the first month after commissioning the scanner, we concentrated on radiation protection, patient selection, preparation, and workflow process. Appropriately, there were few patients who underwent both CTA and CCA. Images obtained were also frequently sub-optimal and affected distal segments and branches. Unfamiliarity with CTA images and planes, plus poor contrast-enhancement of branches, led to misinterpretation of vessel segments. Failure to appreciate the prevalence and significance of coronary calcification led to many ‘false positive’ segments on CTA.

Analyzing the CTA images at the end of 6 months, our accuracy for the detection of coronary disease has increased to over 70% for sensitivity and PPV, and over 95% for specificity and NPV. Compared to established centers however, our sensitivity and PPV for detection of coronary disease by CTA were still much lower. This was due to our low rates of ‘true positives’ in relation to all CCA-proven lesions (sensitivity), and to all CTA-detected lesions (PPV). One reason for this could be the low prevalence of disease in the segments evaluated – around 12% in each quarterly evaluation. Therefore, although the results indicate that we could confidently exclude significant coronary disease if the CTA images were negative (high NPV), we could not use computed tomography to assist us in the confirmation of disease (low PPV). After an additional 3 months, we had doubled the total number of patients with CTA and CCA for comparison, but did not change patient selection, preparation, work flow process, and scan protocol. There was no significant change in any of the measurements of accuracy. Neither have we improved on our ratio of evaluable segments - 87% of the 16-segment coronary tree in Q2 compared to 83% in Q3. From a CTA interpretational point of view we appeared to have reached a plateau.

In October we evaluated a series of scan protocols and workflow processes from other centers and decided to adopt a ‘test-bolus’ method of contrast-enhancement. This method has been shown recently to improve contrast-enhancement of coronary arteries, although not of other major vasculature. Applying this protocol between November and December, patient scan time did not increase significantly, and patients did not have to hold their breath for more than 12 sec. Contrast volumes used were more consistent and significantly less than the ‘bolus-tracking’ method. Performing correlation analysis on just 19 patients to date, we achieved 100% correlation of the 10 major vessel segments. 95% of the entire 16-segment coronary tree could be evaluated, with the remaining 5% excluded due to previous stent implantation (1 segment), heavily calcified segments (5 segments), and missing branch segments (9 segments). The ‘false negative’ occurred in the mid-segment of an obtuse marginal branch in a patient with multivessel disease.

Based on our experience, and in comparison to other published reports, we believe that the new generation 64-row MDCT has improved the feasibility and accuracy of CTA. Our results have further demonstrated the relative contributions of operator experience and protocol selection to the accuracy of CTA analysis. However, formal physician training is necessary and a learning curve has to be overcome before a new center can confidently evaluate CTA, especially when involving difficult coronary segments such as those of small-caliber vessels and calcified plaques. We welcome the recent announcement by the joint task force of the American College of Cardiology and American Heart Association on proposed training guidelines for MDCT coronary imaging and analysis Budoff 2005. Our results indicate that a minimum 6-month supervised training is probably adequate to begin evaluation of CTA images. An understanding of coronary and cardiac anatomy and the pathophysiology of coronary flow and disease, as well as radiation protection, are important pre-requisites to ensuring patient eligibility and safety. Finally, we suggest that centers embarking on CTA must provide safeguards against gross misinterpretation during the period of learning curve. This may be in the form of on-site supervision, or by providing alternative methods of coronary imaging.

Study limitations

We acknowledge that there are large discrepancies in the number of patients from each quarter. This would tend to skew the accuracy rates. It is more likely to reduce accuracy rather than increase it as any false results would be magnified. This is illustrated in Q4 when a single ‘false negative’ result dragged down the NPV. In Q1, we evaluated only the 10 major segments. We also chose to determine the accuracy of CTA using a segment-by-segment instead of per-patient analysis as we felt the former will be more appropriate for a technical report on accuracy. It is likely also that sensitivity for the detection of significant coronary disease may improve further with a per-patient analysis.

Conclusion

A minimum of 6 months learning curve was necessary to interpret 64-row computed tomography-assisted angiography for the detection of coronary disease in our center, with early experience. Further improvements depend upon choice of protocols and workflow process. Centers with less than a year’s experience must determine their own rates of accuracy, and should not quote the accuracy rates reported by more experienced centers.

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References


