FEATURED ARTICLES

Multislice computed tomography to rule out coronary allograft vasculopathy in heart transplant patients

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KEY WORDS:
256-row computed tomography; coronary angiography; heart transplant; multislice computed tomography; coronary allograft vasculopathy

BACKGROUND: This study assessed if invasive coronary angiogram (CA) could be replaced by multislice (64- or 256-row) computed tomography (MSCT) to systematically rule out coronary allograft vasculopathy in heart transplant patients.

METHODS: Electrocardiogram-gated contrast-enhanced MSCT (64-row for the first 25 patients and 256-row for the others) was compared with CA. MSCT parameters, adapted to the patient’s weight, included 120 kV, 800 mAs, 0.625-mm slice thickness, and 0.42/0.27-second rotation time. The primary end point was the negative predictive value (NPV) of MSCT for the detection of significant (> 50%) coronary stenosis. Secondary end points were the comparison of X-ray (mSv) and iodine contrast agent (ml) exposures.

RESULTS: The study prospectively included 102 patients (mean age, 53 ± 14 years). Transplantation occurred 6 ± 5 years before inclusion. At CA, 41.8% had stenosis ≤ 50% and 8% had stenosis > 50%. Among the 1,308 angiographic coronary segments ≥ 1.5 mm, 1,250 (95.6%) were evaluable by MSCT. The NPV of MSCT was 96.6% by patient analysis and 99.7% by segment analysis. The positive predictive value (PPV) was 45.5%. The total volume of contrast agent was 139 ± 43 vs 91 ± 12 vs 56 ± 19 ml (p < 0.05) with 64-row MSCT, 256-row MSCT, and CA, respectively. The effective radiation dose was higher using retrospective gating (17.8 ± 5.5 mSv, p = 0.571) compared with CA (6.0 ± 3.5 mSv).

CONCLUSION: Newer generations of MSCT (64- or 256-row) have a good NPV and may represent an alternative to invasive CA to rule out significant (> 50%) coronary vasculopathy in heart transplant patients, despite a low PPV.

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Heart transplantation represents a breakthrough in the treatment of terminal heart failure (“last chance therapy”), leading to a spectacular improvement of the patients’ prognosis.1 However, coronary allograft vasculopathy (CAV) remains frequent (8% at 1 year, 42% at 5 years) and is the main factor limiting long-term survival after heart transplantation.1–3 This particular CAV is often of immunologic origin (leading to intra-parietal inflammatory arterial changes) but also due to the frequent exposure to classical cardiovascular risk factors (diabetes, high blood pressure, dyslipidemia) caused by the immunosuppressive regimen.4 Its evolution is often rapid and diffuse and remains mostly silent because of the denervation of the transplanted heart.5

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Owing to the weak diagnostic value of non-invasive testing in this setting, the use of invasive coronary angiography (CA) in the systematic screening of CAV is favored.\textsuperscript{6–8} However, CA is an invasive technique carrying the risk of complications.\textsuperscript{9,10}

Newer generations of multislice computed tomography (MSCT) allow increasingly precise non-invasive assessments of the coronary artery tree. If MSCT has been widely studied in the setting of coronary artery disease screening in non-transplant patients who are symptomatic or who have multiple risk factors,\textsuperscript{11–14} only few studies, with low sample size, have been conducted in heart transplant patients.\textsuperscript{15–18} We report a large series conducted with 256-row MSCT in heart transplant recipients. The aim of our study is to demonstrate that MSCT can replace CA to systematically rule out CAV, as defined as significant coronary lesion suitable for percutaneous coronary intervention (PCI).

**Methods**

The protocol for this study was approved by the local Ethics Committee (CPP Ile de France Paris VI), and all patients who participated gave written, informed consent. The study is registered at ClinicalTrials.gov, number NCT01122810.

**Study population**

In our institution, systematic coronary screening by CA is performed in transplant patients regardless of the occurrence of any symptoms. From June 2008 to November 2010, 102 patients were prospectively enrolled in the study at the time of their annual CA. All heart transplant patients aged older than 18 years were eligible. Exclusion criteria were chronic renal failure (creatinine >150 µmol/liter), atrial fibrillation, resting heart rate >100 beats/min, allergy to iodinated contrast agent, and hospitalization for an emergency. Patients who fulfilled the inclusion criteria were invited to have a MSCT 24 hours before their planned annual CA. Blood sampling was performed before MSCT, before CA, the day after CA, and at 72 hours after discharge to assess creatinine levels.

**Data acquisition from MSCT**

MSCT imaging was performed using a 64-row CT for the first 25 patients and with a 256-row CT (both Brilliance, Philips, Eindhoven, The Netherlands) for the rest of the study patients. All MSCT acquisitions were gated to the electrocardiogram (ECG). Negative chronotropic agents (β-blockers, ivabradine) were not used. The standard acquisition protocol included a 420-ms (64-row) or 270-ms rotation time (256-row) and a 0.625-mm slice thickness. An intravenous injection of 85 to 125 ml of iodinated contrast agent (Iomeron [iomeprol], Bracco-Altana Pharma GmbH, Konstanz, Germany) was administered using a dual-head injector (Injektron CT 2, Medtron, Saarbrucken, Germany). Images were acquired using 120 kV and 800 mAs for normal weight. Reconstructions were systematically performed at 40% and 75% of the cardiac cycle, in case of retrospective gating. Additional reconstructions were performed if needed because of calcifications, motion artefacts, or low signal-to-noise ratio at various points in the cycle. If prospective gating was used, reconstruction was performed at 75% of the cardiac cycle. MSCT studies were interpreted by two independent radiologists (D.T., Ph.C.) blinded to the CA results.

The effective dose (ED in mSv) of radiation to the patient was assessed using the dose-length product (DLP in mGy × cm): \( ED = 0.014 \times DLP \).

**Data acquisition from invasive CA**

According to good clinical practice, intravenous hydration with saline 0.09% (1,000 ml/12 hours) was administered in the 12 hours before and after contrast agent injection.\textsuperscript{19} CA was performed according to standard protocol, using as often as possible radial access with 4F or 5 F sheaths. Continuous invasive blood pressure and heart rate monitoring were performed. The amount of iodinated contrast agent (Hexabrix Ioxaglate Meglumine and Ioxaglate Sodium, Guerbet, Villepinte, France) and the dose-area product (DAP in Gy × cm²) were collected. The ED in mSv was assessed as follows: \( ED = 0.2 \times DAP \). CAs were interpreted by 2 interventional cardiologists (O.B., C.L.) blinded to the MSCT results. Quantification of coronary arteries narrowing was performed using quantitative coronary angiography (CASS system, Philips).

**Analysis**

We compared the 2 techniques by patient, by vessel, and by segment. Only segments ≥1.5 mm in diameter were considered for analysis. Each segment was classified as having stenosis (stenosis ≥50%), atheroma (stenosis ≤50%), or as normal.

For in segment-based analysis, we used the modified American Heart Association coronary segment classification (17 segments) for each patient.\textsuperscript{20} The 17 segments were (1) left main coronary artery, (2) proximal left anterior descending artery (LAD), (3) first diagonal, (4) middle LAD, (5) second diagonal, (6) distal LAD, (7) intermediate, (8) proximal left circumflex artery (LCX), (9) first obtuse marginal branch, (10) middle LCX, (11) second obtuse marginal branch, (12) distal LCX, (13) proximal right coronary artery (RCA), (14) middle RCA, (15) distal RCA, (16) posterior descending branch, and (17) posterolateral branch. For in vessel-based analysis, the coronary arteries were divided into left main coronary artery, LAD, LCX, and RCA. Intermediate arteries were classified as additional vessels.

**Statistical analysis**

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of MSCT for the detection of significant stenosis compared with CA was assessed using a 2 × 2 cross-tabulation model. The total amount of iodine contrast agent and X-ray exposure were compared using paired \( t \)-tests. A value of \( p < 0.05 \) was considered statistically significant.

**Results**

From June 2008 to November 2010, 102 patients were prospectively included. Of these, 1 MSCT was not interpretable due to motion artefacts, 1 patient had anaphylactic shock during MSCT (serious adverse event) and did not have CA, and 1 patient refused MSCT after enrollment. One patient did not fulfill the inclusion criteria (hospitalization for an emergency) and was secondarily
excluded. All MSCT imaging was performed 24 hours before CA, except for 1 patient (10 days after).

Baseline characteristics are reported in Table 1 and medications in Table 2. The comparison concerns 98 patients and 416 vessels. At CA, we counted 1,470 segments, with 1,308 segments ≥ 1.5 mm in diameter. MSCT was able to analyze 1,250 segments; thus, the percentage of analyzable segments ≥ 1.5 mm by MSCT was 95.6%. The prevalence of CAV was 41.8 % (atheroma), and 8% had significant stenosis. The diagnostic value of MSCT for the detection of significant coronary stenosis is reported in Table 3.

Patient-based analysis

Among the 98 patients, CA showed 8 (8%) had significant stenosis and 41 (41%) had atheroma. The sensitivity of patient-based analysis was 62.5% and the specificity was 93.3%. PPV was 45.5% and NPV was 96.6%. Among the 44 patients (44%) with normal MSCT, 38 (86%) had normal CA, 5 (11%) had atheroma at CA, and 1 (2%) had significant CAV (occlusion of the distal LAD).

Vessel-based analysis

Among the 416 vessels, CA showed 8 (2%) had significant stenosis and 79 (19%) had atheroma. The sensitivity of vessel-based analysis was 62.5% and the specificity was 98%. The PPV was 38.4% and NPV was 99.3%, respectively.

Segment-based analysis

Among the 1,308 segments, CA showed 10 (1%) were significantly narrowed and 133 (10%) had atheroma. The sensitivity of segment-based analysis was 55.6% and the specificity was 99.5%. The PPV was 38.4% and NPV was 99.7%.

Diagnostic accuracy of 256-row MSCT

In the 74 patients who underwent 256-row MSCT, 955 segments ≥ 1.5 mm could be analyzed compared with 974 at CA, providing a 98% rate of analyzable segments. Six patients (8%) had significant stenoses. Table 4 reports the diagnostic value of 256-row MSCT after excluding the 24 patients who had 64-row MSCT.

False-negative results

There were 3 false-negative results: 1 short (1-mm length) significant stenosis of the proximal LAD was considered as non-significant at MSCT (Figure 1), MSCT did not show 1 significant stenosis of the distal LAD at the site of a coronary fistula to the right ventricle (Figure 2), and 1 significant stenosis of the ostium of the first diagonal was considered as non-significant at MSCT (Figure 3).

Analysis of intra-stent restenosis

Seven patients had a prior PCI, with 13 stents implanted in coronary arteries > 1.5 mm in diameter. Among them, MSCT correctly evaluated 11 stents (85%), ruling out significant restenosis in 10, and correctly diagnosed a stent occlusion in the remaining artery. One stent (mid-LAD) was

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Table 1: Clinical Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD or No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>50 ± 16</td>
</tr>
<tr>
<td>Women</td>
<td>16 (16)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>25 ± 4</td>
</tr>
<tr>
<td>Former smoker</td>
<td>46 (45)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>32 (31)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>27 (26)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11 (11)</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>20 (20)</td>
</tr>
<tr>
<td>Age of transplant, years</td>
<td>6 ± 5</td>
</tr>
<tr>
<td>Initial cardiomyopathy</td>
<td></td>
</tr>
<tr>
<td>Dilated</td>
<td>53 (52)</td>
</tr>
<tr>
<td>Ischemic</td>
<td>24 (23)</td>
</tr>
<tr>
<td>Hypertrophic/restrictive</td>
<td>8 (8)</td>
</tr>
<tr>
<td>Valvular</td>
<td>9 (9)</td>
</tr>
<tr>
<td>Congenital</td>
<td>1 (1)</td>
</tr>
<tr>
<td>ARVC</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Myocarditis</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Others</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Heart rate, beats/min</td>
<td>83 ± 13</td>
</tr>
<tr>
<td>Blood pressure, mm Hg</td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>136 ± 17</td>
</tr>
<tr>
<td>Diastolic</td>
<td>86 ± 11</td>
</tr>
<tr>
<td>Symptoms</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Prior heart transplant vasculopathy</td>
<td>9 (9)</td>
</tr>
<tr>
<td>Prior PCI (stent)</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Electrocardiogram abnormalities</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, %</td>
<td>68 ± 5</td>
</tr>
<tr>
<td>Creatinine clearance, ml/min</td>
<td>76 ± 25</td>
</tr>
</tbody>
</table>

ARVC, arrhythmogenic right ventricular cardiomyopathy; CAD, coronary artery disease; PCI, percutaneous coronary intervention; SD, standard deviation.
not mentioned at MSCT because of motion artefacts, and intra-stent restenosis could not be accurately quantified in another stent (mid-RCA).

**Effective radiation dose**

The average radiation dose with MSCT was 17.2 mSv (range, 4.0–37.8 mSv) using mostly retrospective ECG gating and was similar using 64-row (17.8 mSv) or 256-row CT (17.1 mSv). Three MSCT were performed using prospective ECG gating, with an average effective dose of 6.2 mSv (range, 4.0–7.5 mSv). The average effective dose of CA was 6.0 mSv (range, 1.4–21.0 mSv), which was significantly lower compared with retrospective MSCT (p < 0.05), however, it remained in the same range compared with prospective MSCT (p = 0.571).

**Contrast agent**

The average amount of iodinated contrast agent was significantly lower with CA than with MSCT (56 ± 19 vs 103 ± 31 ml; p < 0.05) Imaging with 256-row CT was associated with a significant 34% reduction of iodinated contrast agent volume compared with 64-row CT (91 ± 12 vs 139 ± 43 ml; p < 0.05).

**Safety concerns**

No serious adverse events occurred except 1 patient with anaphylactic shock during MSCT, which was treated successfully with appropriate medication. Mean creatinine clearance was 76 ± 35 ml/min at baseline vs 74 ± 23 ml/min at day 5 after double iodine injection (p = 0.357). Transient creatinine raise (+30 μmol/liter) occurred in 6 patients, with spontaneous resolution in the days after. CA performed mostly by radial access (85%) was safe, without any vascular or allergic complications.

**Discussion**

We have reported a large series of new generations of MSCT scanners compared with CA in heart transplant patients. We found that 64-row and 256-row MSCT images have good specificity and NPV to rule out significant CAV needing PCI. A normal result on MSCT may dispense of the need for invasive CA in heart transplant patients. However, short lesions, ostia lesions, and coronary fistulae represent situations where MSCT must be carefully analyzed. In addition, safety concerns remain concerning the effective radiation dose and the total amount of iodinated contrast agent in the setting of annual assessment.

**Screening of CAV**

CAV is a frequent condition after heart transplantation and a major prognostic marker. Because non-invasive tests (stress test, stress echography, single photon-emission computed tomography) have a poor diagnostic value and CAV is often silent, CA remains the gold standard for screening and is usually performed annually. Adding intravascular ultrasound imaging increases the ability to detect CAV, but with the risk of adverse procedural events (coronary dissection, thrombosis). Myocardial blush assessment has also been reported as a possible early marker of CAV, indicative of microvasculature impairment before epicardial disease. Optical coherence tomography may also improve the diagnostic accuracy of CA. However, CA is an invasive technique and complications, especially at the vascular site,
have been reported, leading to much debate regarding the need for assessment as often as yearly. Global improvements have been made in the safety of invasive CA, however. In our experience, 85% had CA by radial approach. It is now well established that the radial approach reduces access site-related complications compared with the femoral approach. None of our patients had arterial access complications or an allergic reaction during CA. The effective radiation dose and the amount of contrast agent were also very low.

Diagnostic accuracy of MSCT

Diagnostic accuracy of MSCT has been widely studied in large populations of non-transplant patients, yielding controversial results. Owing to the low prevalence of heart transplant patients coupled with the high frequency of exclusion criteria (ie, renal failure, rhythm disorder), few have been included in prospective studies of MSCT compared with CA. This explains the modest number of studies, with small sample sizes, that have been conducted to date in the field using 16-row or 64-row MSCT. Our study found MSCT had a high NPV for the diagnosis of significant CAV (segment ≥ 1.5 mm) in heart transplant patients in sinus rhythm, ranging from 96.6% in patient-based analyses to 99.7% in segment-based analyses. The 256-row MSCT showed an even higher NPV of 98.4% to 99.9% with a specificity of 92.6% to 99.3%, confirming results found in previous analyses with smaller sample sizes and earlier generations of MSCT. Unlike MSCT used for the positive diagnosis of coronary artery disease in a at-risk non-transplant population, low sensitivity and PPV are not a concern for the purpose of ruling out CAV. Indeed, transplant patients are all on intense secondary prevention therapy (Table 2), whatever their coronary anatomy, given the high incidence of cardiovascular risk factors and CAV. Moreover, no specific treatment is available to stop CAV, although everolimus shows promising results. Whether their coronary arteries are normal or atheromatous is of little additional value in these well-treated patients, whereas excluding significant CAV suitable for revascularization (segment ≥ 1.5 mm) may be of major importance. Our results, in accordance with others, show that a normal result on MSCT could avoid the need for invasive CA in heart transplant patients. In addition, the cost-effectiveness of this strategy has already been shown.

The International Society for Heart and Lung Transplantation (ISHLT) recently established a standardized nomenclature for CAV based on visual CA assessment of the coronary tree, allograft function, and physiology carrying a prognostic significance. Given that coronary “branch vessel” assessment is not adequate with MSCT, the ISHLT Working Group does not recommend use of MSCT for CAV classification. Our experiment and that of other teams does not contradict this recommendation: MSCT appears relevant to rule out significant CAV on clinically significant coronary arteries suitable for PCI; however, secondary branch vessels sized < 1.5 mm were not analyzed. Thus, the high NPV value of MSCT for significant stenosis on main branches suitable for PCI may avoid unnecessary invasive CAs. However, after an initial CA, MSCT may help to assess ISHLT CAV nomenclature by assessing progression or occurrence of CAV, as left ventricular ejection fraction, in transplant patients and adds a prognostic value.

Situations at risk of misdiagnosis with MSCT

However, some false-negative results of MSCT occurred. In real life, those misdiagnoses would certainly not have led to “loss of chance” for these patients. Indeed, 2 MSCTs showed atheroma (instead of significant stenosis), and 1 MSCT missed a distal lesion into a coronary fistula. These 3 situations would have led physicians to further assess coronary anatomy by CA. However, although infrequent (3%), it raises concern regarding the possible misdiagnosis with MSCT in certain cases, namely millimeter-length lesions, ostial lesions (for which MSCT spatial resolution may be impaired), and coronary fistulae (a situation not infrequent in heart transplant patients needing repeated endomyocardial biopsies). The awareness of these limitations should help to improve non-invasive screening of CAV in transplant patients.
Evaluation of intra-stent restenosis remains difficult and depends on stent size, strut thickness, and stent material. In our experience, only 85% of the stents were correctly evaluated by MSCT, but the number of stents was small. Our experience does not support the use of MSCT for the systematic screening of stented patients. Further improvement of MSCT and stent—with thinner strut and new material—should improve intra-stent restenosis assessment.

Future improvements

New generations of MSCT with short rotation time (especially for the 256-row MSCT) allow the performance of valuable non-invasive assessment of the coronary anatomy, even in patients with a high resting heart rate. The mean resting heart rate was 83 ± 13 beats/min in our study, and no negative chronotropic agents were used. This improvement is also reported with dual-source MSCT, leading to very short rotation time and allowing short, whole-heart acquisition. Another way the diagnostic value of MSCT may improve could be with the emergence of perfusion imaging. Moreover, MSCT, in addition to the analysis of the vessel lumen, has also been shown to be able to characterize atherosclerotic plaque unlike CA.

Safety concerns

In the setting of yearly coronary evaluation, safety concerns remain concerning repeated radiation and iodine exposures with MSCT as with CA. In our preliminary experiment, we preferably performed retrospective acquisition to test the feasibility of MSCT. This kind of acquisition leads to a higher effective dose compared with CA. However, prospective ECG-gated acquisition showed a similar effective dose compared with CA and therefore should be used to rule out routine CAV.

Cumulative radiation exposure remains an important issue in transplant patients exposed to multiple ionizing radiation from various imaging and cardiac procedures. The estimated rate of malignancy is approximately 15% at 5 years in this population. However, the increase in cancer risk attributable to cumulative radiation exposure seems to remain very low (0.34% additional risk) compared with malignancy linked with immunosuppression and has to be balanced with the diagnostic interest of the ionizing procedures. Furthermore, MSCT enables additional analyses not supported by CA, including morphologic and functional study of the heart, pulmonary parenchyma study for malignancy screening, and bone density of the spinal column to assess corticosteroid-induced bone disease.

Higher volume of contrast agent is still needed with MSCT in our experience; however, the improvement in rotation time provided by 256-row MSCT or a dual-source CT scanner, which enables complete coverage of the heart in a single heart rate beat in a duration of only 0.6 seconds (so-called Flash mode), allows a volume reduction of 33%.

This study has some limitations. This was a single-center study with preliminary experience of 256-row CT. MSCT was upgraded during the course of the study, and the results of the 64- and 256-row were pooled. However, upgrading a 64-row to a 256-row MSCT only shortens the rotation time without any improvement of the spatial resolution.

Although this is a large series in the specialty of heart transplantation, the number of patients remains limited—as heart transplantation frequency itself—and the prevalence of significant CAV is quite low due to the exclusion criteria. To avoid iodine-related nephrotoxicity, patients with renal failure were excluded; however, they often are the older transplant patients carrying the highest risk of CAV. These findings are not uncommon in other experiences showing prevalences ranging from 10% to 20% in populations of only tens of patients, reflecting the difficulty of conducting large studies in the field.

In conclusion, newer generations of MSCT (64-row or 256-row) have a good NPV for the systematic rule-out of significant (>50%) CAV in heart transplant patients. For this purpose, MSCT can represent an alternative to invasive CA in patients without significant coronary stenosis suitable for PCI. However, the PPV of MSCT remains low, and MSCT should be interpreted carefully in patients with short lesions, ostial lesions, or arteriovenous fistulae. This technique cannot yet be recommended in the evaluation of symptoms but may allow non-invasive screening in symptom-free transplant patients. Future improvement (perfusion imaging) should increase the diagnostic accuracy of MSCT. Safety concerns, including contrast agent volume and radiation exposure, remain in the setting of annual coronary assessment, and future developments should address this issue.

Disclosure statement

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The authors dedicate this study to M.R.M., a 67-year-old heart transplant patient, and to his family, who died after multiple cerebral embolisms occurring after systematic annual coronary angiogram. May our study contribute to a safer assessment of coronary anatomy in heart transplant patients.

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