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Leiden

The Netherlands

Multimodality Imaging of Anatomy and Function in Coronary Artery Disease

Schuijf, J.D.

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Part II

Defining Patient Populations

II B

After Revascularization

Chapter 9

Feasibility of Assessment of Stent Patency using 16-Slice Computed Tomography

Joanne D. Schuijf, Jeroen J. Bax, J. Wouter Jukema, Hildo J. Lamb,
Hazem M. A. Warda, Hubert W. Vliegen, Albert de Roos,
Ernst E. van der Wall

Abstract

Background

Intracoronary stent implantation is a frequently performed procedure in the treatment of stenoses in coronary arteries, although in-stent restenosis still occurs in approximately 20%. A non-invasive diagnostic procedure to evaluate in-stent restenosis would therefore be of great benefit. The purpose of this study was to demonstrate the feasibility of assessing stent patency using 16-slice Computed Tomography.

Methods

In 22 patients with previously implanted stents, Multi-Slice Computed Tomography (MSCT) was performed. For each stent, assessability was determined and related to stent type and diameter. Subsequently, the presence of significant restenosis was determined in the evaluable stents. In addition, peri-stent lumina (5.00mm proximal and distal to the stent) were also evaluated. Conventional angiography in combination with quantitative coronary angiography (QCA) served as the standard of reference.

Results

MSCT was performed successfully in all but one patient. Of 65 stents, 50 (77%) were determined assessable. Uninterpretable stents tended to have a thicker strut thickness and/or a smaller diameter. In the evaluable stents, 7 of 9 stenoses were detected and the absence of restenosis was correctly identified in all 41 patent stents, resulting in a sensitivity and specificity of 78% and 100%, respectively. Sensitivity and specificity for the detection of peri-stent stenosis were 75% and 96%, respectively.

Conclusion

MSCT may be useful in the assessment of stent patency and may function as a gatekeeper prior to invasive diagnostic procedures.

Introduction

Although promising results have been obtained using Multi-Slice Computed Tomography (MSCT) for the detection of coronary artery stenoses^{1,2}, imaging of metallic stents is technically difficult, and not much data are available. Stent-related high-density artifacts lead to artificial narrowing of the lumen, leaving only a small portion of the lumen visible^{3,4}. However, the recently introduced 16-slice CT systems allow simultaneous acquisition of 16 submillimeter slices, which has led to improved spatial resolution. In combination with the increased temporal resolution due to faster rotation times, stent assessability is thus likely to improve, which has already been demonstrated *in vitro*⁵. Recent advances in stent design are also likely to result in improved stent assessability. The purpose of this study was to demonstrate the feasibility of assessing coronary stent patency using 16-slice MSCT.

Methods

Patients and study protocol

The study group consisted of 22 consecutive patients who had previously undergone percutaneous transluminal coronary angioplasty (PTCA) treatment in combination with stent placement. Exclusion criteria were: 1). atrial fibrillation, 2). renal insufficiency (serum creatinine >120 mmol/L), 3). known allergy to iodine contrast media, 4). severe claustrophobia, and 5). pregnancy. All patients underwent a cardiac MSCT examination for the evaluation of stent patency. Conventional catheter-based coronary angiography with QCA analysis was performed prior or after MSCT and served as reference standard. All patients gave written informed consent to the study protocol, which was approved by the local ethics committee.

Data acquisition

Cardiac MSCT was performed on a Toshiba Multi-slice Aquilion 16 system (Toshiba Medical Systems, Tokyo, Japan) with a collimation of 16 x 0.5 mm and a rotation time of 0.4 or 0.5 s, depending on the heart rate. The tube current was 250 mA, at 120 kV. Non-ionic contrast material was administered in the antecubital vein with an amount of 120-150 ml, depending on the total scan time, and a flow rate of 4.0 ml/sec (Xenetix 300®, Guerbet, Aulnay S. Bois, France). Automated peak enhancement detection in the aortic root was used for timing of the bolus. Images were acquired during inspiratory breath hold preceded by mild hyperventilation. During the CT examination, the electrocardiogram was recorded simultaneously for retrospective gating of the data. With the aid of a segmental reconstruction algorithm, data of 2 or 3 consecutive heartbeats were used to generate a single image. To evaluate the coronary arteries, 5 separate reconstructions covering diastole (65% - 85%) were obtained with an effective slice thickness of 0.5 mm and a reconstruction interval of 0.4 mm. If motion

artifacts were present in one of the coronary arteries, additional reconstructions were made at 40%, 45% and 50% of the cardiac cycle. Images were transferred to a remote workstation (Vitrea2, Vital Images, Plymouth, Minn. USA) for post-processing. For each individual coronary artery, the data set containing no or minimal motion artifacts were used for further evaluation.

Conventional X-ray coronary angiography was performed according to standard techniques. Vascular access was obtained using the femoral approach with the Seldinger technique and a 6- or 7-French catheter.

Data analysis

For the assessment of coronary stents, both the original axial CT images and curved multiplanar reconstructions were evaluated by an experienced observer blinded to the catheterization results. First, each stent was assigned an image quality score of: 1 (poor image quality or uninterpretable), 2 (adequate image quality) or 3 (good image quality). Subsequently, the presence of significant restenosis ($\geq 50\%$ reduction of lumen diameter) was assessed in the evaluable stents. A stent was considered patent if both distal run-off was present and contrast medium could be detected within the stent. In case of doubt, cross-sections were also taken into account. In addition, the presence of peri-stent stenosis, $\geq 50\%$ or $\geq 70\%$ narrowing of luminal diameter 5.00 mm proximal and distal to the stent, or, in case of overlapping stents, the stented segment, was evaluated.

Conventional angiograms were evaluated by an experienced observer without knowledge of the MSCT data. Subsequently QCA was performed of both the stent or stented vessel and their proximal and distal lumina according to a standard algorithm (QCA-CMS version 5.2, Medis, Leiden, The Netherlands)⁶.

Statistical analysis

To relate stent assessability to stent type, stents were divided in either large (>3.00 mm) or small (≤ 3.00 mm) diameter stents and stents with either thick (≥ 140 μm) struts or thin (<140 μm) struts. Subsequently, percentage assessable stents and average image quality were calculated for each category. Sensitivity and specificity for the detection of restenosis $\geq 50\%$, as determined by visual inspection of conventional angiograms, were determined for each stent and stented coronary artery. A separate analysis was performed per vessel, since in several patients (partially) overlapping stents or even completely stented vessels were present, thus hampering individual assessment. A stented vessel was considered assessable, when at least one stented segment was interpretable. Stented side-branches were also included in the analysis. In addition, sensitivity and specificity were also determined for the detection of significant ($\geq 50\%$) or high-grade ($\geq 70\%$) narrowing of the peri-stent lumina (5.00 mm proximal and distal to the stent). For this analysis, QCA served as the standard of reference.

Results

Clinical characteristics of the study group

Twenty-two patients (20 men, aged 63 ± 7 years), with a total of 68 stents (1 to 9 stents per patient, average 3 ± 2.8), scheduled for invasive coronary angiography, were investigated. The average interval between MSCT and conventional angiography was 3 ± 2 days. All patients had previously undergone PTCA with stent implantation. Seventeen patients (77%) were on continuous beta-blocker medication, and no additional beta-blockers were administered. The patient characteristics are summarized in Table 1.

Table 1. Clinical characteristics of the study population (n=22).

	n (%)
Male/Female	20/2
Age (years)	62 ± 7
Heart Rate (bpm)	65 ± 11
Single vessel coronary disease	4 (18%)
Multi-vessel coronary disease	18 (82%)
Previous myocardial infarction	14 (64%)
Previous coronary angioplasty	22 (100%)
Previous Coronary Bypass Grafting	3 (14%)
Beta-Blocker	17 (77%)
Angina Pectoris	
CCS class 1/2	4 (18%)
CCS class 3/4	18 (82%)
Heart Failure	
NYHA class 1/2	18 (82%)
NYHA class 3/4	4 (18%)
Stent location	
Left Main	1 (1%)
Left Anterior Descending	28 (41%)
Left Circumflex	5 (7%)
Right Coronary Artery	28 (41%)
Saphenous Vein Graft	6 (9%)

Values are n (%).

CCS: Canadian Cardiovascular Society; NYHA: New York Heart Association;

Stent characteristics

A total of 68 stents was studied, of which 23 implanted more than one month before and 6 placed in coronary bypass grafts. On average, MSCT was performed 14 ± 26 months (range 0 – 2469 days) after stent implantation. Diameter of implanted stents ranged from 2.25 to 5.0 mm. Fourteen different stent types were present: Ave (S660 and S670, Medtronic) 11, Driver (Medtronic) 4, Wiktor Hepamed (Medtronic) 2, Ultra (Guidant) 3, Zeta (Guidant) 9, Penta (Guidant) 1, Tristar (Guidant) 4, Achieve (Guidant) 2, Orbus (Orbus technologies) 3, R-stent (Orbus technologies) 2, Cypher (Cordis) 23, Bx Velocity (Cordis) 2, Bx Sonic (Cordis) 1, and Express (Boston Scientific) 1.

MSCT

MSCT was performed successfully in all but one patient. In this patient, the electrocardiographical signal was lost during data acquisition and this patient was therefore excluded from analysis.

Of the remaining 65 stents, 50 (77%) were of sufficient quality to assess patency. Reasons of uninterpretability were motion artifacts, metal artifacts, small size of the stent, severe calcifications or a combination of the above. Average image quality score was 2.7 ± 0.7 for stents with a diameter

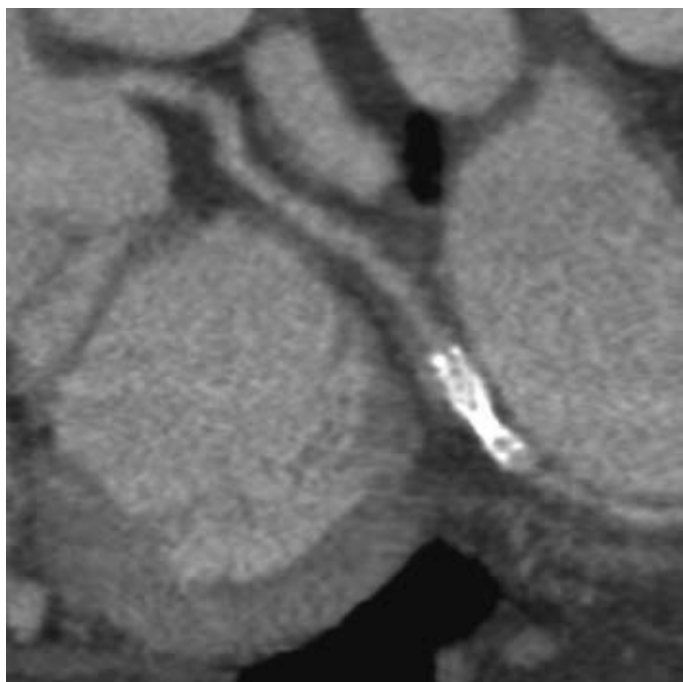


Figure 1. Example of a curved multiplanar reconstruction of an uninterpretable stent placed in the distal left circumflex. Due to high-density artifacts of the thick struts of the stent, the lumen is obscured in a large part of the stent, rendering it uninterpretable.

>3.0 mm, in contrast to an average of 2.2 ± 0.9 for stents with a diameter ≤ 3.0 mm. Of the stents with a thick strut thickness (≥ 140 μm), 11 (41%) were uninterpretable, whereas 34 (89%) of stents with thin struts were assessable. Figure 1 shows an example of an uninterpretable stent with a thick strut thickness.

Restenosis ($\geq 50\%$ of lumen diameter reduction) was correctly ruled out in 41 stents (Figure 2). MSCT identified 7 stents with restenosis correctly. However, in 2 stents, distal to occluded stents, the presence of restenosis was not observed on MSCT. Accordingly, the sensitivity and specificity for the assessment of patent/stenotic stents were 78% and 100%, respectively. When the uninterpretable stents were included in the analysis, the overall sensitivity remained 78%, whereas the specificity decreased to 73%. Details are summarized in Table 2.

Table 2. Individual stent analysis.

	n (%)
Total stents	65
Assessable	50 (77%)
Sensitivity	7/9 (78%)
Specificity	41/41 (100%)
Uninterpretable stents	15
diameter ≤ 3.0 mm	13
diameter > 3.0 mm	2
strut thickness < 140 μm	4
strut thickness ≥ 140 μm	11
Interpretable stents	50
diameter ≤ 3.0 mm	33
diameter > 3.0 mm	17
strut thickness < 140 μm	34
strut thickness ≥ 140 μm	16

In 8 patients, overlapping stents or even completely stented vessels were present, thus hampering individual stent assessment. Therefore, analysis was also performed per coronary artery or side-branch individually (Table 3). In 4 patients, one or more coronary arteries were uninterpretable. Thus, 29 stented vessels (81%) were available for evaluation. Significant in-stent restenosis ($\geq 50\%$) was correctly detected in 3 vessels (1 left anterior descending and 2 right coronary arteries). Absence of restenosis was correctly identified in the remaining 26 patent coronary arteries. Therefore, on a per patient basis, the presence or absence of significant in-stent restenosis was correctly identified in all patients.

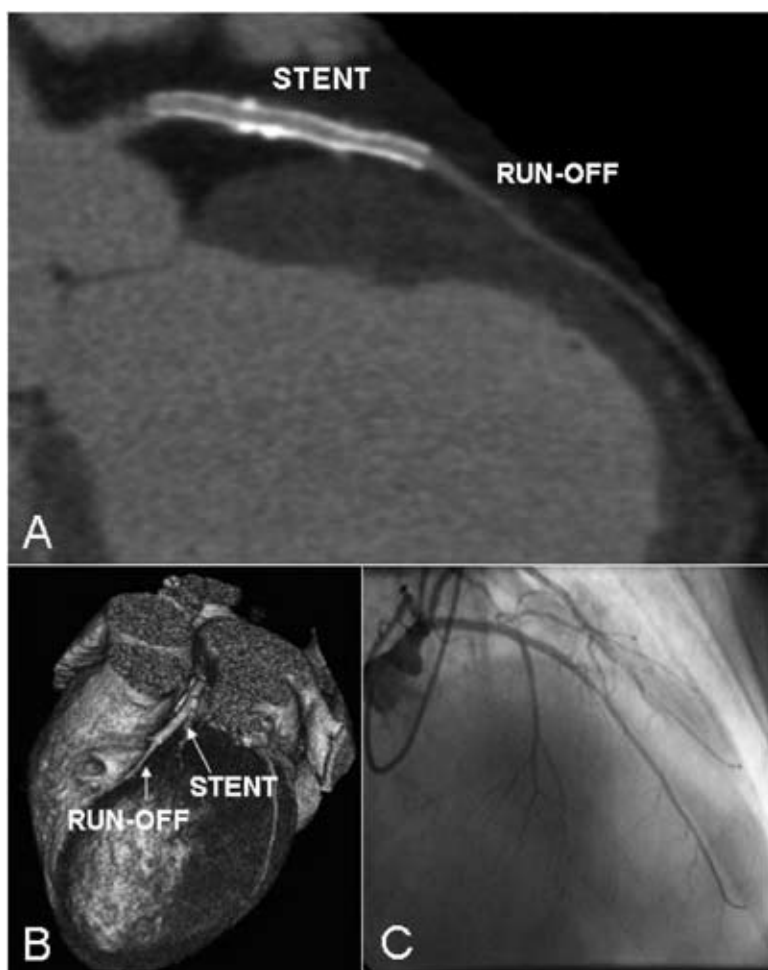


Figure 2. Example of a patent stent in the left anterior descending. In panel A, a curved multiplanar reconstruction is shown, which reveals a patent stent, as also evidenced by the distal run-off. Also in panel B, a three-dimensional volume rendered reconstruction, distal run-off is clearly present. Findings were confirmed by conventional angiography (panel C).

In 2 patients, both the left anterior descending and the diagonal branch were stented, resulting in only one proximal stent lumen and two distal stent lumina. In 6 other stented arteries, both the proximal and distal lumina were uninterpretable and in one patient, only the proximal part of a stent, placed in the distal left circumflex, could be evaluated. Therefore, 57 of 70 peri-stent lumina were available for evaluation. Narrowing of $\geq 50\%$ (as determined by QCA) of the peri-stent lumen was correctly ruled out in 51 of 53 peri-stent lumina and 3 of 4 significant narrowings were also found on the MSCT images. One of these significant narrowings, however, was underestimated by MSCT, and when the threshold was increased to high-grade stenosis ($\geq 70\%$), sensitivity decreased therefore to 50%. Specificity, however, increased from 96% to 100%.

Table 3. Diagnostic accuracy to detect significant in-stent or peri-stent restenosis (per vessel analysis).

		All branches	Left Main	Left Anterior Descending	Left Circumflex	Right Coronary Artery	Saphenous Vein Graft
Stents							
(≥50%)	Total	36	1	15	5	13	2
	Assessable	29 (81%)	1 (100%)	12 (80%)	3 (60%)	11 (85%)	2 (100%)
	Sensitivity	3/3 (100%)	-	1/1 (100%)	-	2/2 (100%)	-
	Specificity	26/26 (100%)	1/1 (100%)	11/11 (100%)	3/3 (100%)	9/9 (100%)	2/2 (100%)
Persistent							
	Total	70	2	28	10	26	4
(≥50%)	Assessable	57 (81%)	2 (100%)	22 (79%)	7 (70%)	22 (85%)	4 (100%)
	Sensitivity	3/4 (75%)	-	0/1 (0%)	-	2/2 (100%)	1/1 (100%)
	Specificity	51/53 (96%)	2/2 (100%)	20/21 (95%)	7/7 (100%)	19/20 (95%)	3/3 (100%)
(≥70%)	Sensitivity	2/4 (50%)	-	0/1 (0%)	-	2/2 (100%)	0/1 (0%)
	Specificity	53/53 (100%)	2/2 (100%)	21/21 (100%)	7/7 (100%)	20/20 (100%)	3/3 (100%)

Values are n (%) and include side-branches.

Discussion

The purpose of this study was to demonstrate the feasibility of stent patency assessment using 16-slice MSCT. A total of 65 stents was evaluated, of which 50 (77%) were of sufficient image quality to assess patency. As expected, stents with thicker struts were found to be more prone to high-density artifacts (and thus decreased assessability) than stents with a thin strut thickness. The effect of diameter on assessability was even more pronounced: 13 out of 15 (87%) uninterpretable stents had a diameter $\leq$ 3.0 mm. Stents with a large diameter are more likely to be evaluable since a sufficient portion of the stent lumen will remain visible despite artificial narrowing.

In the evaluable stents, we demonstrated a good sensitivity and specificity for the detection of significant in-stent stenosis. Furthermore, the presence or absence of significant in-stent stenosis was correctly identified in all patients. Therefore, our results indicate that, although detection of subtle in-stent hyperplasia remains impossible, qualitative assessment of coronary stents is feasible using 16-slice MSCT. In particular, the presence of contrast enhancement of the vessel distal to the stent is a potent sign of patency, while the near absence of distal run-off almost certainly indicates severe stenosis or total stent occlusion.

An important limitation of the present study is that similar to previous studies concerning the assessment of stent patency, only a small number of patients (14%) with significant in-stent restenosis was present. Therefore, our data concerning the sensitivity for detecting in-stent restenosis have to

be interpreted with care and more data are needed to precisely determine the sensitivity of MSCT in the detection of in-stent restenosis. Still, as evidenced by the high specificity, the current data suggest that 16-slice MSCT may be useful in the assessment of stent patency, especially in patients with large diameter stents. Since a substantial amount of all coronary angiograms are not followed by an intervention, MSCT could play an important role in excluding in-stent restenosis and thus function as a gatekeeper prior to invasive diagnostic procedures.

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