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ORIGINAL PAPER

Coronary CT angiography (CCTA) using third-generation dual-source CT for ruling out in-stent restenosis

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Abstract

Aims Late in-stent restenosis (ISR) has become increasingly important, in particular due to neo-atherosclerosis. CCTA is a highly sensitive method for detecting coronary plaques. Its diagnostic accuracy regarding ISR is controversial. Stent artifacts can impede image quality, but recent developments in CT-technology may help to overcome some of these problems and allow for improved diagnostic accuracy.

Methods Consecutive patients after previous coronary revascularization who had stable symptoms or signs of possible disease progression were examined using a third-generation dual-source CT scanner. After the scan, patients were followed for clinical events (MACE) over a mean of 399 days. Patients with high-grade stenoses were referred for invasive coronary angiography (ICA), unclear findings were further evaluated either by ICA or functional testing.

Results Overall, 226 patients were included. A total of 457 stents were evaluated (2.0 ± 1.4 per patient). Mean stent diameter was 2.9 ± 0.45 mm. In 61%, a high-pitch protocol was employed. Mean dose-length product (DLP) of CCTA was 159.2 mGy cm, corresponding to 2.2 mSv using a conversion factor of $k = 0.014$. Mean amount of contrast agent was 58.3 ± 12.5 ml. In 145 patients (64%), CCTA was negative. In this group, one MACE occurred (acute coronary syndrome) during follow-up in a patient who had also undergone unremarkable ICA. In 23 patients (10%), CCTA detected 28 ISR which were confirmed and treated by ICA (true positive). In 27 patients (12%), ISR was suspected by CCTA but excluded by ICA (false positive), 30 patients (13%) had unclear findings and normal non-invasive tests. No MACE occurred during follow-up in these patients. One patient was misclassified in CCTA as having intermediate and not high-grade ISR who underwent revascularization within 3 months. Eleven patients (5%) were lost to follow-up. During follow-up, eight patients had myocardial infarctions due to five ISRs and three de novo lesions. No patient died. In cases with unclear or false-positive findings, the amount of stents was significantly higher, stents were smaller and patients had a higher BMI.

Conclusion In almost two-thirds of symptomatic patients with previous coronary stent implantation, ISR could be ruled out by CCTA. 10% of patients had definite ISR. The rate of false-negative findings was low (< 1%), whereas the rate of false positive or inconclusive findings was 25%, leading to invasive rule-out of ISR by ICA in 12%. CCTA appears valuable as a tool for safely excluding ISR. It might help to avoid invasive diagnostic procedures. Further analyses are warranted, in particular regarding the influence of stent dimensions and the total amount of stents in a patient.

Keywords Coronary computed tomography angiography · Coronary stents · In-stent stenosis · BMS · DES · Third-generation dual-source CT

Introduction

Percutaneous coronary stent implantation (PCI) is a widely used treatment of stable coronary artery disease (CAD) besides optimal medical treatment (Fig. 1). Complications encompass stent thrombosis and in-stent restenosis (ISR), especially due to neoatherosclerosis (NA) [1, 2] (Fig. 2). In a randomized controlled trial, stent thrombosis occurred in 3% of patients who had received an everolimus-eluting

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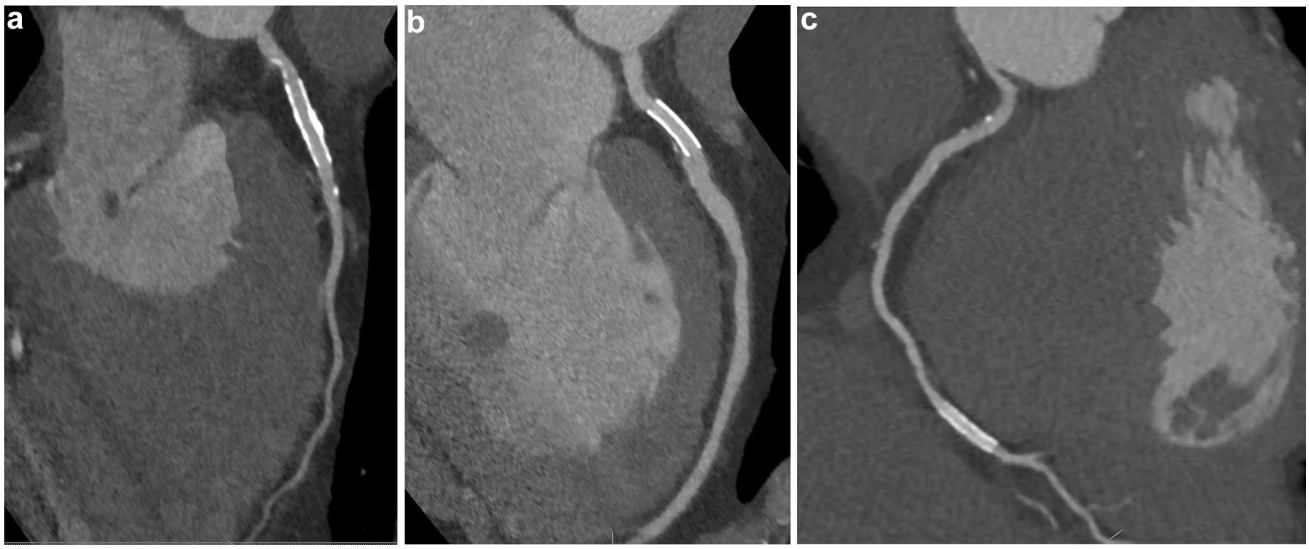

Fig. 1 Different patients with patent stents in CCTA. **a** 64-year-old patient with Resolute 3.0/18 mm DES in LAD 2 years after implantation. **b** 55-year-old patient with 3.0/15 mm DES in LAD 2 years after implantation. **c** 75-year-old patient with 2.75/15 mm DES in distal RCA 2 years after implantation. *CCTA* coronary computed tomography angiography, *DES* drug-eluting stent, *LAD* left anterior descending, *RCA* right coronary artery

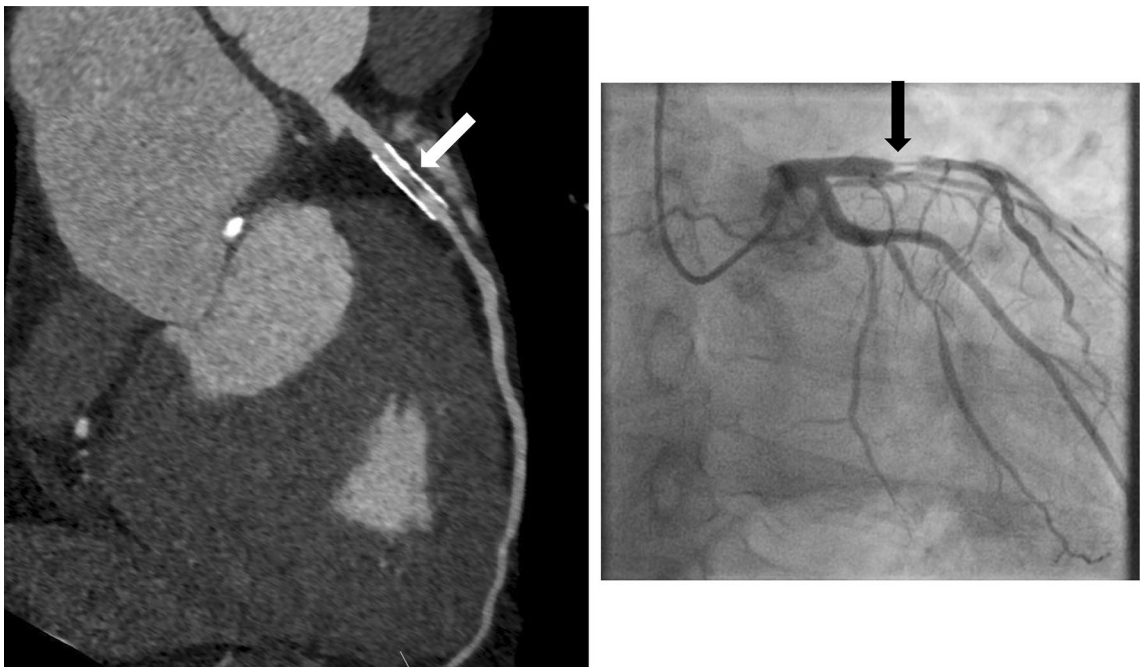

Fig. 2 High-grade in-stent stenosis (3.5/18 mm Promus DES) in a 59-year-old patient. He presented with atypical chest pain 6 years after stent implantation in LAD. High-grade ISR (arrows) was confirmed and treated by invasive angiogram. *DES* drug-eluting stent, *LAD* left anterior descending, *ISR* in-stent stenosis

stent and in 6% of patients with paclitaxel-eluting stents after 5 years [3]. NA is an issue of interest because it develops within months and years after stent implantation, whereas atherosclerosis in native arteries appears after decades [4]. It is the most important cause of late in-stent thrombosis and despite the development of stents from bare-metal stents (BMS) to (first and second generation) drug-eluting stents (DES) NA still affects all kind of stents. Remarkably, DES seem to be more prone to NA, possibly due to delayed arterial healing [4]. Stent thrombosis can lead to acute coronary

syndromes but its prevalence has decreased, especially in second-generation drug-eluting stents (DES) [5].

Non-invasive functional tests such as exercise ECG, stress echocardiography or perfusion MRI are recommended in symptomatic patients after coronary revascularization. Sensitivities and specificities of these tests vary between 45–94% and 61–95%, respectively [6]. In clinical follow-up of patients with symptoms suggesting progression of CAD results are often inconclusive. The combination of low prevalence of in-stent thrombosis and less than perfect sensitivity and specificity leads to false negative and especially false-positive findings, often resulting in invasive coronary angiography (ICA).

Coronary CT angiography (CCTA) has been established as a non-invasive method for detecting coronary atherosclerosis in symptomatic patients with a low to intermediate pretest probability (i.e., 15–50%) or unclear stress imaging test results [6]. There have been remarkable improvements in temporal and spatial resolution over the past decade. So far, clinical use has not been advocated in patients with coronary stents, because stents can cause relevant artifacts such as beam-hardening and blooming, thus limiting diagnostic evaluability. Most CT-studies in patients with previous revascularization used first or second-generation (64-slice-) scanners [7–12]. Sensitivities and specificities for detecting high-grade in-stent stenosis have varied between 87–95% and 81–98%, respectively [7–9]. For systems providing 2×128 slices, sensitivity and specificity were 94–100% and 65–92%, respectively [13–15]. Negative predictive values were high in all studies, ranging between 96–100%. Diagnostic accuracy was significantly higher in these studies when only stents with diameters ≥ 3.0 mm were included.

Third-generation dual-source multi-detector systems with higher spatial and temporal resolution are the current state-of-the-art. Good image quality could be demonstrated even in patients with high-coronary calcium scores (Agatston score < 2000) independent of heart rate or body habitus [16]. To our best knowledge, studies with these scanners regarding evaluation of coronary stents have not been performed so far. We assessed the feasibility of third-generation dual-source CCTA in symptomatic patients for detecting in-stent restenosis (Fig. 3). Furthermore, the outcome after CCTA diagnosis was evaluated.

Methods

Patients

Between June 2014 and July 2016, 226 consecutive patients with stable coronary artery disease (SCAD) were examined after previous percutaneous coronary intervention (PCI) using stents of diameters ≥ 2.5 mm (BMS and DES). Patients with coronary bypass grafts were not included. They were

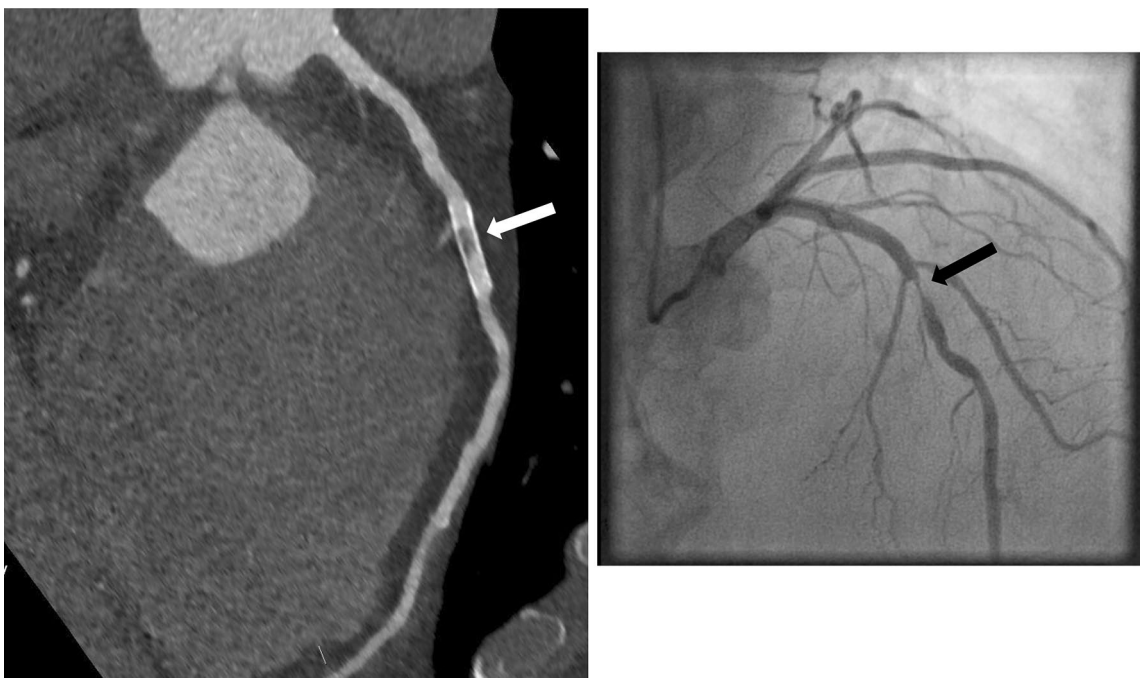

Fig. 3 High-grade in-stent stenosis (3.0/16 mm Taxus DES in LAD) in a 78-year-old man 11 years after implantation. The patient presented with presyncopal episodes but no typical angina. High-grade ISR (arrows) was confirmed and treated by invasive angiogram. *DES* drug-eluting stent, LAD left anterior descending

referred by their treating cardiologist either as an out or in-patient because of symptoms or signs of possible disease progression (i.e. angina, shortness of breath, changes in ECG, etc.). In case in-stent stenoses > 50% was diagnosed, they were referred for invasive coronary angiography (ICA). Unclear findings were further evaluated either by ICA or functional testing. After the initial diagnostic work-up, patients were followed for clinical events (MACE) for at least 1 year either on the basis of a follow-up appointment, by standardized questionnaires or phone calls. MACE occurring > 90 days after CCTA were considered to be independent of the baseline diagnostic procedures. Cardiovascular risk factors such as age, body mass index (BMI), systemic hypertension, hypercholesterolemia, smoking, diabetes mellitus, and family history of CAD were assessed. Types of the stents, stent length, diameter and date of implantation were documented.

CCTA and protocol

All CT datasets were obtained using a third-generation dual-source CT system (SOMATOM Force, Siemens Healthineers, Forchheim, Germany). The system provides $2 \times 192 \times 0.6$ mm collimation and a gantry rotation speed of 250 ms. Non-contrast-enhanced scan at 120 kV was performed prior to angiography with a threshold of 130 HU for obtaining Agatston-Score. In case of very severe calcification, CT-angiography was cancelled. This decision was made individually on the basis of calcification pattern and potential focal plaques rendering lumen analysis impossible. There was no fixed threshold of the Agatston Score that would prevent contrast-enhanced scanning. Obviously, stented portions of the vessel could not be evaluated regarding quantification of coronary calcification so that the total Agatston Score was computed only outside these areas and accordingly was incomplete. Slice thickness was 3.0 mm. Contrast agent transit time was measured using test-bolus technique in the ascending aorta using 10 ml followed by 50 ml of normal saline. Afterwards, a prospectively ECG-triggered high-pitch spiral ("Turbo Flash") acquisition or sequential mode was performed in a cranio-caudal scan direction at 70–120 kV using "CARE kV" (Siemens Healthineers, Forchheim, Germany). 40–50 ml of contrast agent (Imeron 350, Bracco Imaging, Konstanz, Germany) were injected for angiography in an antecubital vein at a flow rate of 5 ml/s followed by a 50 ml flush of normal saline at the same flow. In case of severe motion artifacts using the high-pitch mode, scans were repeated using a sequential scanning mode. Beta blockers (atenolol p.o. or metoprolol i.v.) were administered prior to the scan in case of heart rates above 60–65/min in the absence of contraindications. All patients were treated with nitroglycerin 0.8 mg sublingually for coronary vasodilatation after being positioned on the scanner table. Images were reconstructed using iterative reconstruction strength ADMIRE 2 (ADMIRE, Siemens Healthcare, Forchheim, Germany) with 0.5 mm slice thickness, an increment of 0.3 mm, a medium soft convolution kernel (Bv36) and a medium-sharp kernel (Bv49). Datasets of axial slices and multiplanar reformations were obtained. Two experienced readers (one radiologist and one cardiologist) analyzed all series using commercially available software (Syngo Via VA30A, Siemens Healthcare, Forchheim, Germany). Tube voltage, the amount of contrast agent, and dose-length product (DLP) were assessed and reported.

The study was performed in accordance with a vote from the local ethic committee.

Statistical analysis

All statistical analyses were performed using SPSS software (Version 24, IBM, Armonk, NY, USA). For binary variables, counts and percentages were calculated. For continuous variables, the median and standard deviation were computed. Mann–Whitney test was used for comparisons between assessable stents and false-positive/unclear findings. A p value < 0.05 was considered significant.

Results

Overall, 226 patients were included (196 male, 57 female). Mean age was 67.1 ± 10.5 years. Two-third of patients had hypertension, nearly half had hyperlipidemia or were treated with statins. Mean BMI was 27 kg/m^2. Patient characteristics are shown in Table 1.

A total of 457 stents were evaluated (2.0 ± 1.4 per patient), 50% of stents had been placed in left anterior descending artery (LAD). Mean diameter was 2.9 ± 0.45 mm, mean time since implantation 4.8 ± 3.9 years. Mean stent length was 16.2 ± 5.9 mm. For 96 stents (21%), either stent type or

Table 1 Patient characteristics

	n	%
No. of patients	226	
Female patients	57	25
Age, years	67.1 ± 10.5	
Body mass index, kg/m^2	26.9 ± 4.9	
Hypertonus	152	67
Diabetes mellitus	35	16
Dyslipidemia	108	48
Current smoker	32	14
Family history CAD	51	23

CAD coronary artery disease

characteristics (length, diameter) were missing. Stent characteristics are shown in Table 2.

In 61% of the patients, a high-pitch protocol was employed, covering the complete heart in diastole during one cardiac cycle (scan time 160 ms). 36% of patients were examined using an adaptive sequential mode ("step and shoot"). In seven patients (3%), repeated scanning using adaptive sequential mode was necessary due to image quality, especially motion artifacts in the high-pitch mode. Median kV was 90 (25th, 75th percentile values: 80, 100). Mean total dose-length product (DLP; localizer, calcium score and test bolus included) of CCTA was 159.2 mGy cm, corresponding to 2.2 mSv using a conversion factor of $k = 0.014$. Mean amount of contrast agent was 58.3 ± 12.5 ml. Detailed CCTA parameters are shown in Table 3.

Follow-up was complete in 215 patients (95%). Eleven patients were lost to follow-up (patients from other countries, missing or erroneous contact details). Mean follow-up was 399 days (±192). 40% of those patients with complete follow-up were seen as out-patients, 39% were evaluated using a standardized questionnaire, and 21% were contacted by phone calls.

In 144 patients (64%), CCTA was negative, and no MACE occurred during follow-up. 24 patients of that group had de novo stenoses and were revascularized, but ISR could be ruled out (Fig. 4). One patient had negative CCTA and ICA, but an acute coronary syndrome (ACS) due to ISR occurred after five months. In 23 patients (10%), CCTA detected 28 ISR (Fig. 5). These were confirmed and treated by ICA (true positive). In 27 patients (12%), ISR was suspected by CCTA but excluded by ICA (false positive). 30 patients (13%) had unclear findings and normal non-invasive tests. The vast majority of additional testing consisted of stress magnetic resonance imaging (using adenosine infusions). Two patients underwent nuclear studies (technetium-99m sestamibi SPECT). No MACE occurred during follow-up in these patients. One patient was misclassified in CCTA as having intermediate and not high-grade ISR and underwent revascularization within 3 months. Results are summarized in Table 4.

Characteristics of stents showing ISR are shown in Table 5. Mean diameter was also 2.9 mm (±0.4). Mean time since implantation was 6.7 years (±4.6). Six stents were BMS, Nine stents first-generation DES, 11 stents second-generation DES. Two stents could not be classified.

Stents that showed unclear results or false-positive findings (ISR was ruled out by ICA) were significantly smaller. Mean diameter was 2.83 mm compared to 2.94 mm for true-positive/true-negative stents ($p = 0.034$). Mean BMI was significantly higher in this group (28.02 versus 26.66 kg/m^2, $p = 0.025$). Patients with false-positive/unclear findings had significantly more stents than patients with true-positive/true-negative stents [median: 3.0 (1.0–4.0) versus 1.0 (1.0–2.0), $p < 0.001$].

During extended follow-up (i.e. > 3 months after CCTA), eight patients had myocardial infarctions due to five ISR and three de novo lesions. Eleven patients (5%) were lost to

Table 2 Stent characteristics

	n	%
No. of stents	457	
LM	4	1
LAD	228	50
RCX	94	21
RCA	131	29
Mean diameter	2.9 ± 0.5	
Mean length	16.2 ± 5.9	
BMS	99	
First-generation DES	109	
Second-generation DES	193	
Time since implantation	4.8 ± 3.9	

56 stents could not be classified regarding BMS/DES because of lacking data

LM left main, *LAD* left anterior descending, *RCX* ramus circumflexus, *RCA* right coronary artery, *BMS* bare-metal stent, *DES* drug-eluting stent

Table 3 CCTA parameters

	n	%
High-pitch mode	137	61
Adaptive sequential	82	36
Both, repeated scan	7	3
	Mean	SD
Tube voltage (kV)	89	13
Contrast agent (ml)	58	13
DLP (mGy cm)	159	161

DLP dose-length product

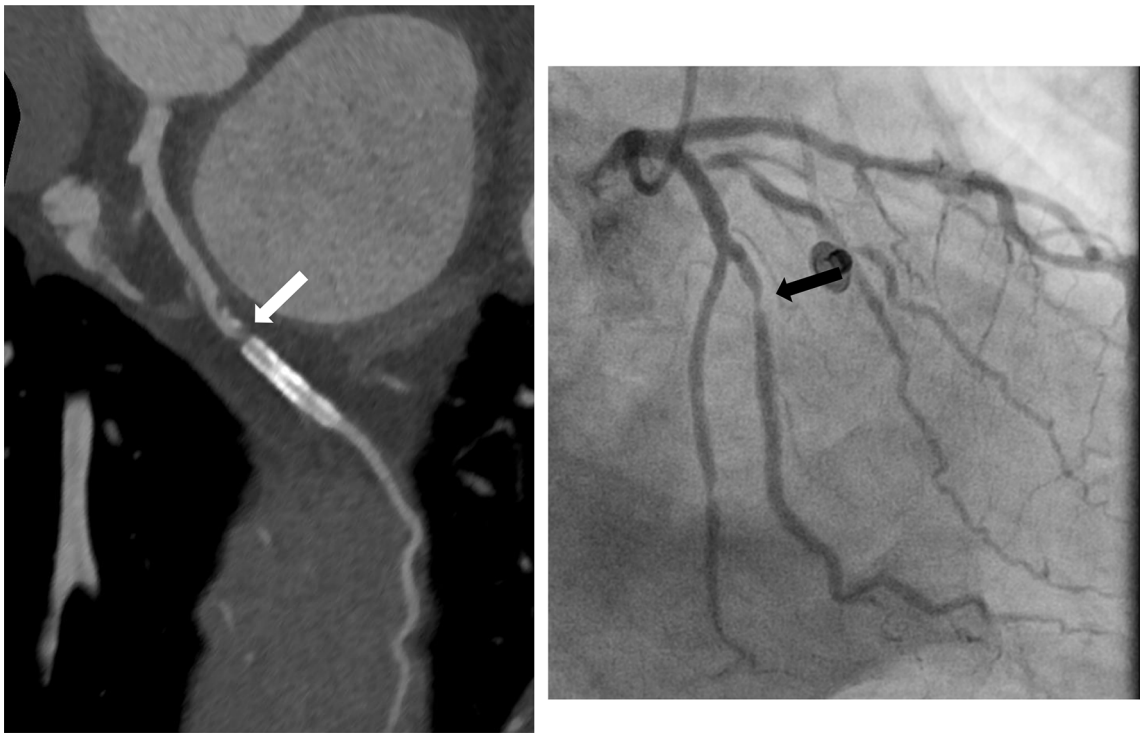

Fig. 4 High-grade stenosis proximal to the stent in the left posterolateral branch of left circumflex artery (arrow). The 64-year-old man presented with typical angina 3 years after implantation of a Promus 2.75/12 mm DES in. The invasive angiogram confirmed the stenosis (arrow), the patient was treated with another DES proximal to the implanted stent. *DES* drug-eluting stent

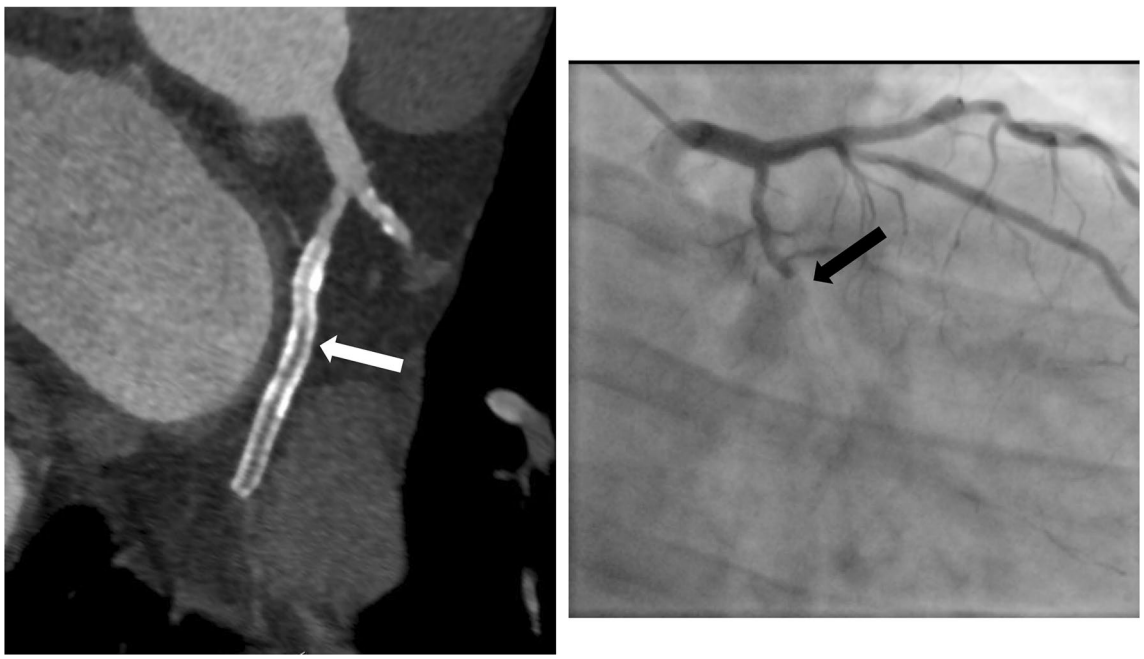

Fig. 5 51-year-old patient with complete in-stent occlusion of left circumflex artery (arrow). Two BMS had been implanted 2 years before in acute coronary syndrome with reanimation due to ventricular fibrillation. Recanalization was tried but wire passage through the occluded stents (arrow) was not possible. *BMS* bare-metal stent

Table 4 Results

	ICA/MACE positive	ICA/MACE negative
CCTA positive	23	57
CCTA negative	1	144

One patient is not classified due to negative CCTA and negative ICA 9 weeks later. ACS occurred 5 months after negative CCTA and 3 months after negative ICA due to ISR

Table 5 Stent characteristics showing ISR

	n
Mean diameter (mm)	2.9 (±0.4)
Mean length (mm)	18.1 (±7.2)
Time since implantation (days)	2442 (±1690)
BMS	6
First-generation DES	9
Second-generation DES	11
Not classified stent	2

ISR in-stent stenosis, *BMS* bare-metal stent, *DES* drug-eluting stent

follow-up because they came from other countries. To our best knowledge, no patient died.

Discussion

Our study demonstrates that CCTA using the latest scanner generation is able to exclude ISR reliably. In almost two-third of patients, ISR could be ruled out and no further tests were necessary. Negative predictive value was high. This is in agreement with the previous studies [7, 8] or metaanalysis [10], respectively. No MACE occurred during follow-up in this group.

Since the prevalence of severe ISR is quite low, a diagnostic test should be reliable in ruling out ISR. Due to the high-negative predictive value, CCTA appears to be a promising tool in that respect. ISR was found and treated in 10% of patients. The event rate was very low and included myocardial infarctions in eight patients during extended follow-up (> 3 months after CCTA). Only one patient was misclassified using CCTA who had to be revascularized after ICA had been performed.

In 25% patients, further tests (either ICA or functional tests) were necessary to rule out ISR in our study. False positive and unassessable stents were smaller in diameters and mean BMI in these patients was higher. Furthermore, significantly more stents were implanted in these patients. In patients with multiple stents, overlap of stent struts can impede image quality by causing artifacts. These patients may have a more advanced disease and, thus, more calcification compared to patients with one single stent. Further studies are necessary to examine that influence.

It could be demonstrated in previous studies that in stents with small diameters (< 3.0 mm) artifacts can impair image quality [7, 8]. The number of false positive or unassessable stents might be reduced, and thus diagnostic accuracy be increased, by performing CCTA in patients with wider stents ≥ 3.0 mm who have normal BMI and not multiple stents with overlapping struts. Exact cutoffs remain unclear, further studies on these parameters are necessary. It is noteworthy, however, that only 27 patients (12%) of our cohort had ICA showing normal coronary arteries/patent stents. Unnecessary invasive procedures could be avoided in almost two-third of patients using CCTA.

In the course of the development of CT scanners, radiation dose and the amount of contrast media have decreased over the last years [17]. Mean radiation dose in our cohort was 2.2 mSv and thus even lower than in the German cardiac CT registry. The frequent application (> 60%) of a high-pitch scan protocol in our study contributed to the improved radiation exposure. Total amount of contrast media could also be reduced using fast scanners. In this study, it ranged below 60 ml per patient. Procedural risk of CCTA, therefore, appears to be low.

Coronary computed tomography angiography is the only non-invasive examination for visualizing the wall of the coronary arteries. Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) are the diagnostic gold-standard for coronary atherosclerosis but they require invasive procedures with potential harm to the patient. Because of the scope of the problem, a reliable and safe diagnostic method is needed. The development of neoatherosclerosis and the progression of atherosclerosis in native coronary arteries are closely associated [18]. Signs of NA could be demonstrated on OCT in 16% of patients 5 years after stent implantation. Non-target lesion revascularizations were significantly more frequent in patients showing NA. It is, therefore, crucial to identify patients with disease progression in coronary stents and in native coronary arteries since NA and atherosclerosis of native arteries seem to go hand in hand. CCTA can be a useful tool for that. With respect to the actual scanner, the visible stent lumen can be enhanced by using sharp or medium-sharp convolution kernels (like Bv49) [19]. Moreover, one study demonstrated that "subtraction CCTA"—which is performed using three-dimensional images before and after application of contrast agent—might improve assessment of stents at the expense of a higher radiation exposure [20]. However, more studies and new developments of image reconstruction concerning enhanced visibility of stent lumina are necessary.

One strength of this study is the large cohort of patients. Examinations were performed in patients with suspected

progression of CAD after clinical assessment. They were all referred to CCTA after cardiological evaluation. All CT datasets were included—not only assessable images as in previous studies. The focus was on the clinical course of the patients. Procedures were made according to clinical practice and radiation exposure was not increased by performing additional ICA to confirm the results.

There are several limitations: Findings were not compared with ICA (and OCT/IVUS), that is why we did not calculate sensitivities, specificities or predictive values. We cannot exclude ISR that might be missed on CCTA. However, over a follow-up of > 12 months, there was no sign of an increased event rate in patients deemed to have patent stents. However, this was not a controlled trial. One possible confounding factor was the fact that some patients with severe localized coronary calcifications were not included. Evaluation of stent patency in these patients would have been more difficult and the successful rule-out rate of ISR might have been lower. However, some patient selection before CCTA represents current clinical practice and is indeed useful to avoid unnecessary exposure to radiation and contrast media. Furthermore, results of CCTA were reported to the cardiologist and consequently influenced further treatment. The indication for ICA or other diagnostic tests were at the discretion of the treating physician. Eleven patients were lost to follow-up, mainly because they moved or lived abroad.

Further randomized tests for patients after stent implantation are warranted to confirm performance of CCTA, especially versus functional tests and regarding the influence of stent dimensions or overlap of stents.

Conclusion

Coronary computed tomography angiography using a third-generation dual-source CT scanner seems to be safe for ruling out ISR, in particular in patients with larger stent diameter > 3.0 mm, rather single than multiple stents, and normal BMI. The majority of patients does not need further testing. Using CCTA, it is possible to avoid unnecessary invasive procedures.

Compliance with ethical standards

Conflict of interest There are no conflicts of interest of any of the contributing authors.

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