



Reducing both radiation and contrast doses in coronary CT angiography in lean patients on a 16-cm wide-detector CT using 70 kVp and ASiR-V algorithm, in comparison with the conventional 100-kVp protocol

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Received: 1 July 2018 / Revised: 28 September 2018 / Accepted: 17 October 2018 / Published online: 30 November 2018
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Abstract

Objective To investigate the value of prospectively ECG-triggered coronary CT angiography (CCTA) for lean patients with body mass index (BMI) ≤ 23 kg/m² using 70 kVp and high-level volume-based adaptive statistical iterative reconstruction (ASiR-V) algorithm on a 16-cm wide-detector CT system for reducing both radiation and contrast doses in comparison with the conventional 100-kVp protocol.

Materials and methods Thirty patients (group A) were prospectively enrolled to undergo 70-kVp CCTA on a 16-cm wide-detector CT scanner with noise index (NI) of 36 HU and at weight-dependent contrast dose rate of 16 mg I/kg/s for 9-s injection. Images were reconstructed with 80% ASiR-V. Radiation dose, contrast dose, and image quality were statistically compared with 30 patients (group B) in database with matching BMI who underwent conventional 100-kVp CCTA with NI of 25 HU, and at 25 mg I/kg/s rate for 10-s injection and reconstructed with 60% ASiR-V.

Results There was no significant difference in patient demographics between the two groups (all $p > 0.05$). The two groups also had similar mean CT values and contrast-noise ratio (CNR) and subjective image quality (all $p > 0.05$). However, group A with 70 kVp reduced the effective dose by 75.3% compared with group B (0.43 ± 0.20 mSv vs. 1.74 ± 1.01 mSv, $p < 0.001$), and required 42.4% less contrast dose than group B (22.46 ± 2.94 ml vs. 38.99 ± 5.10 ml, $p < 0.001$).

Conclusions Prospectively ECG-triggered CCTA using 70 kVp and high-level ASiR-V on a 16-cm wide-detector CT system provides diagnostic images with substantial reduction in both radiation and contrast doses for patients with BMI ≤ 23 kg/m² compared to the conventional 100-kVp protocol.

Key Points

- 70-kVp CCTA produces excellent images at sub-millisievert radiation.
- 70-kVp CCTA reduces both radiation and contrast doses over conventional protocol.
- Achieving low-dose CCTA with combined low kVp and high-level ASiR-V.

Keywords Computed tomography angiography · Coronary angiography · Radiation dosage · Contrast media

Abbreviations

AF Atrial fibrillation
ASiR-V Volume-based adaptive statistical iterative reconstruction

BMI Body mass index
bpm Beats per minute
CAD Coronary artery disease
CAS Coronary artery stenosis
CCTA Coronary CT angiography
CM Contrast medium
CNR Contrast-noise ratio
CTDIvol Volumetric CT dose index
DLP Dose-length product
HR Heart rates
MIP Maximum intensity projection
NI Noise index
ROI Region of interest
SD Standard deviation

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SNR Signal-to-noise ratio
 VR Volume rendering

Introduction

Coronary CT angiography (CCTA) on multislice detector systems has been established as an effective minimally invasive diagnostic method for the evaluation of patients with suspected coronary artery disease [1, 2]. However, radiation dose exposure in CCTA has always been of particular concern because of its possible harmful effect, especially for young patients [3]. There are several approaches to reduce the radiation dose, such as the use of automatic tube current modulation [4], prospective ECG-gating technique [5], adaptive detector collimation with high pitch [6], and iterative reconstruction algorithms [7]. At the same time, the risk of contrast-induced nephropathy (CIN) [8, 9] when using contrast medium also concerns people. The use of lower tube voltages (i.e., 80 kVp and 100 kVp) is an effective strategy to address both of these concerns, reducing not only radiation dose but also contrast dose [10, 11]. Some of the newer CT systems provide even lower tube voltage at 70 kVp, pushing the average photon energy closer to the k-edge of iodine. The recently introduced 256-row, 16-cm wide-detector CT system is equipped with the 70-kVp tube voltage station and a new-generation volume-based adaptive statistical iterative reconstruction (ASiR-V) algorithm to control image noise. The purpose of this study was to investigate the value of combining the 70-kVp tube voltage and ASiR-V algorithm on this 16-cm wide-detector CT system for reducing both radiation and contrast doses for patients with lean body mass index (BMI) without limiting by heart rate or heart rate variability, in comparison with the conventional 100-kVp CCTA protocol.

Materials and methods

Study population

Our study was approved by the institutional review board and all participants gave written informed consent. This was a prospective study of consecutive patients with known or suspected coronary artery disease (CAD) who underwent CCTA scans in the period from October 2017 to March 2018. Only patients with BMI ≤ 23.0 kg/m² were enrolled in our study. Exclusion criteria included pregnancy, hypotension (systolic blood pressure ≤ 90 mmHg), known allergy to iodinated contrast material, renal insufficiency (creatinine ≤ 120 μ mol/l), and inability to cooperate with CCTA scans. According to the inclusion and exclusion criteria, a total of 30 patients were enrolled in the study group (group A) for scanning at 70-kVp tube voltage. For comparison purpose, 30 consecutive patients with matching

BMI values and similar examination indications were retrospectively identified from our hospital database. These patients underwent CCTA between May 2017 and October 2017 using the conventional 100-kVp tube voltage protocol.

Scan protocols

All scans were performed on a 16-cm wide-detector Revolution CT scanner (GE Healthcare) in free-breathing [12] and within one heartbeat using the prospective ECG-triggered axial scan mode. Both groups used 0.28-s rotation speed and automatic tube current modulation for obtaining a preset noise index at 0.625-mm slice thickness and injected with contrast agent Iopamidol (370 mgI/ml, Bracco Imaging Italia S.r.L.). The maximal z-axis coverage of the detector was up to 16 cm. The coronary arteries were scanned with a 12-, 14-, or 16-cm detector collimation according to heart size, for axial coverage from 1 cm below tracheal carina to the bottom of the heart. The acquisition windows for cardiac scans were automatically selected by the scanner and were dependent on the patient heart rates (HR) just before CCTA: 70–80% of the R-R interval for HR < 65 bpm, 30–50% for HR > 80 bpm, and both 30–50% and 70–80% for HR between 66 bpm and 80 bpm. All scans were acquired with bolus-tracking and automatic triggering technique and scans were triggered at a threshold of 220 HU for descending aorta with a scan delay time of 1.6–2.2 s after triggering. CCTA images were reconstructed using the new-generation volume-based adaptive statistical iterative reconstruction (ASiR-V) algorithm for image noise reduction and the Snapshot freeze (SSF) reconstruction technique for cardiac motion correction. The best cardiac phase for generating images was automatically selected by using the Smartphase technique [13] provided by the CT system. There were differences in scan mode and contrast injection protocol for the two groups. Group A used 70-kVp tube voltage, NI of 36 HU, and at a reduced weight-dependent contrast dose rate of 16 mg I/kg/s for 9-s injection. Group B used a conventional scan protocol with 100 kVp, NI of 25 HU, and at the 25 mg I/kg/s contrast dose rate for 10 s. ASiR-V at a level of 80% (80% ASiR-V) was used for image reconstruction in the 70-kVp group and the standard 60% (60% ASiR-V) in the 100-kVp group.

Image quality evaluation

Objective and subjective image qualities were assessed for all patients in a blinded and randomized fashion on an Advanced Workstation (ADW4.6, GE Healthcare). The volume rendering (VR), curved planar reformat (CPR), and maximum intensity projection (MIP) images at 0.625-mm thickness were generated for image quality assessment and comparison. All segments ≥ 1.5 mm in diameter were evaluated. CT attenuation value and standard deviation (SD) of the aortic root, proximal right coronary artery (RCA), left anterior descending (LAD), left

circumflex (LCX), and adjacent epicardial fat were measured on the axial images using region of interest (ROI) of 10–200 mm². The signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR) for vessels were calculated using fat as the background with the SD value of fat as the background noise.

Two radiologists (with 7 years and 1 year of experience in diagnostic CCTA) were blinded for scan modes and independently assessed all CCTA images regarding the overall image quality (vessel enhancement and image noise) and diagnostic confidence on a per-patient level using a 5-point scoring system: (1, non-diagnostic, poor image quality, poor attenuation, and unacceptably high image noise; 2, difficult to diagnose, fair image quality, fair attenuation, and above average noise; 3, diagnosable, moderate image quality, moderate attenuation, and average image noise; 4, good image quality, good attenuation, and less than average noise; 5 excellent image quality, excellent attenuation, and minimal image noise). In addition, the per-vessel and per-segment image quality was also assessed based on the American Heart Association (AHA)–modified 16-segment classification [14] in terms of vessel boundary sharpness and the presence of motion artifacts using a 5-point scale [15]: 5, excellent image quality, clear vessel boundary and display, no motion artifact; 4, good image quality, mostly clear boundary, only a small amount of motion artifacts, not affecting the diagnosis; 3, suboptimal image quality but interpretable, can be used for diagnosis, may affecting the diagnostic accuracy; 2, poor image quality and difficult to perform vessel analysis; 1, non-diagnostic, poor image quality with severe motion artifacts. Images with 3 points or higher were considered to have diagnostic quality. If there was disagreement in image quality assessment between the two reviewers, consensus was reached after negotiation to obtain a final image quality score and the original scores from the two reviewers were tested for consistency. The lowest score from the segments of a vessel was used as the image quality score for the vessel.

Radiation dose calculation

The volumetric CT dose index (CTDI_{vol}) in milligray and dose-length product (DLP) in milligray-centimeter of CT scans were recorded by the system after each scan and the effective dose (ED) in millisieverts (mSv) was estimated as the product of the dose-length product (DLP) in milligray-centimeter and a conversion coefficient of 0.014 mSv mGy⁻¹ cm⁻¹ [16].

Statistical analysis

Continuous variables were expressed as means ± standard deviations (SD) and statistical analyses were performed using SPSS software (SPSS v. 21.0, IBM Corp.). The Mann-Whitney *U* test was used to compare the per-vessel and per-patient image quality scores and the unpaired *t* test was used to compare the

continuous variables, including CT value, CNR, radiation dose, and contrast dose between the two groups. Kappa test was used to evaluate the inter-observer consistency of subjective scores by the two reviewers, and the Kappa values were defined as follows: 0–0.20, slight agreement; 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; and 0.81–1.00, almost perfect agreement. A *p* value of less than 0.05 was considered statistically significant.

Results

Patient characteristics

All 60 patients in our study successfully completed their CCTA examinations without any complication. There was no difference in age (years) (52.8 ± 9.8 vs. 57.4 ± 10.7), mean heart rate (bpm) (69.1 ± 14.4 [range, 48–128] vs. 66.3 ± 14.7 [range, 45–113]), weight (kg) (57.7 ± 7.6 vs. 58.1 ± 7.4), or body mass index (kg/m²) (22.0 ± 2.3 vs. 21.2 ± 2.1) (Table 1). More than 50% of the patient population had a documented history of hypertension or a history of smoking in both groups. The distribution of the main diagnosis was similar in both groups. The main diagnoses of the initial reports were confirmed in the consensus reading in all cases. Coronary artery stenosis (CAS) was found in 21 patients in group A and in 22 patients in group B: 3-vessel lesions in six patients in group A and in five patients in group B; 2-vessel lesions in ten patients in group A and in seven patients in group B, and 1-vessel lesions in five patients in group A and in ten patients in group B. Patient information and dose information are summarized in Table 1.

Image quality evaluation

There were 869 coronary segments from the 60 patients in our study with diameters greater than 1.5 mm. Among these segments, 98.1% (852/869) were evaluable, consisting of 97.0% (415/428) in group A and 98.4% (434/441) in group B. The mean CT values in all vessels were greater than 280 HU in both groups. There were no statistically significant differences in mean CT values in any major vessels between the two groups (415–527 HU in group A vs. 404–517 HU in group B). Group A had a slightly higher background image noise (23.7 ± 3.6 HU) than group B (21.6 ± 3.5 HU) (*p* < 0.05), but this did not significantly impact the SNR and CNR value comparison, nor the subjective image quality comparison. There were no statistically significant differences in SNR and CNR values for any major vessels between the two groups (all *p* > 0.05) (Table 2). In addition, there were also no significant differences in the respective scores in the assessment of the overall image quality and diagnostic confidence on a per-patient level, nor in the assessment of the spatial resolution

Table 1 General information and main clinical history and findings for patients in the two groups

	A (n = 30)	B (n = 30)	T value	p value
General information				
Average age (years)	52.8 ± 9.8	57.4 ± 10.7	- 1.714	0.092
Female	13 (43.3%)	11 (36.6%)	- 0.776	0.441
Weight (kg)	57.7 ± 7.6	58.1 ± 7.4	- 0.173	0.863
Body mass index (kg/m ²)	22.0 ± 2.3	21.2 ± 2.1	- 8.110	0.063
Mean heart rate (bpm)	69.1 ± 14.4	66.3 ± 14.7	0.756	0.453
Contrast doses (ml)	22.46 ± 2.94	38.99 ± 5.10	- 15.376	< 0.001
CTDIvol (mGy)	2.20 ± 0.35	8.79 ± 4.94	- 7.058	< 0.001
DLP (mGy-cm)	31.28 ± 4.94	124.56 ± 72.10	- 6.875	< 0.001
ED (mSv)	0.43 ± 0.20	1.74 ± 1.01	- 6.875	< 0.001
Main clinical history				
Hypertension	15 (50.0%)	16 (53.3%)	0.254	0.800
Family history of heart disease	7 (23.3%)	5 (16.7%)	- 1.385	0.171
History of smoking	16 (53.3%)	17 (56.7%)	0.255	0.799
Type II diabetes	5 (16.7%)	3 (10.0%)	0.750	0.456
Atrial fibrillation	2 (6.7%)	0	- 1.439	0.155
Clinical findings (presence of CAS)				
3-vessel CAS	6	5	- 0.328	0.744
2-vessel CAS	10	7	- 0.850	0.399
1-vessel CAS	5	10	1.494	0.141
Negative	9	8	- 0.282	0.779

Values are mean ± SD (median), n (%); CAS coronary artery stenosis

and motion artifacts caused by the cardiac motion on the per-vessel level between group A and group B (Tables 3 and 4, Figs. 1 and 2). The interrater agreement of the inter-observer was excellent (all *k* > 0.80) (Table 3).

Table 2 CT value, signal-noise ratio (SNR) value, contrast-noise ratio (CNR) value, and subjective quality between the two groups

Measurements	A (n = 30)	B (n = 30)	T value	p value
CT (HU)				
Aortic root	526.7 ± 42.2	517.4 ± 38.7	0.889	0.377
RCA	475.9 ± 44.0	462.7 ± 32.7	1.138	0.193
LAD	452.2 ± 35.8	443.0 ± 29.0	1.098	0.277
LCX	415.1 ± 18.6	404.6 ± 22.4	1.977	0.053
SD _{fat}	23.7 ± 3.6	21.6 ± 3.5	2.290	0.026
Signal-noise ratio				
RCA	16.6 ± 2.7	18.0 ± 3.4	- 1.784	0.080
LAD	16.7 ± 2.0	18.1 ± 2.8	- 2.155	0.053
LCX	16.2 ± 2.6	17.0 ± 3.0	- 1.430	0.158
Contrast-noise ratio				
RCA	24.2 ± 7.0	26.7 ± 5.5	- 1.549	0.127
LAD	23.2 ± 6.7	25.9 ± 4.9	- 1.805	0.076
LCX	21.7 ± 6.1	24.1 ± 4.3	- 1.987	0.052

RCA right coronary artery, LAD left anterior descending, LCX left circumflex

Radiation dose and contrast dose

There was a significant difference in CTDIvol between group A (2.20 ± 1.28 mGy) and group B (8.79 ± 4.94 mGy) (*p* < 0.05), resulting in 75.3% reduction in effective dose for the 70-kVp group (group A) (0.43 ± 0.20 mSv vs. 1.74 ± 1.01 mSv, *p* < 0.001). Moreover, the contrast dose for group A was significantly lower than that for group B (22.46 ± 2.94 ml vs. 38.99 ± 5.10 ml) (*p* < 0.001), a reduction of 42.4%, (Table 1).

Discussion

In our study, we demonstrated that for patients with BMI ≤ 23 kg/m², the use of the 70 kVp in combination with a volume-based adaptive statistical iterative reconstruction (ASiR-V) algorithm could substantially reduce effective dose (by 75.3% to 0.43 from 1.74 mSv) and contrast agent (by 42.4% to 22.46 from 38.99 ml) in CCTA scanning without impairing image quality and diagnostic confidence compared with a conventional 100-kVp protocol.

As the potential health risk of using high radiation exposure or high concentration of iodine load has been demonstrated recently in several studies [17, 18], methods for reducing both radiation dose and contrast dose as much as possible while ensuring image quality have been proposed including the use of automatic tube current modulation and iterative reconstructions. An effective

Table 3 Image quality score distributions between the two reviewers in group A and group B

	Score distribution (1/2/3/4/5)					
	Group A (n = 30)		k value*	Group B (n = 30)		k value**
	Reviewer 1	Reviewer 2		Reviewer 1	Reviewer 2	
Overall image quality	0/0/3/20/7	0/0/4/18/8	0.87	0/0/2/20/8	0/0/2/19/9	0.93
RCA	0/0/4/19/7	0/0/3/18/9	0.81	0/0/4/16/10	0/0/4/15/11	0.94
RCA	0/0/4/20/6	0/0/3/19/8	0.80	0/0/3/18/9	0/0/2/18/10	0.88
LCX	0/0/5/18/7	0/0/5/17/8	0.94	0/0/4/17/9	0/0/4/18/8	0.94

* κ values between the two reviewers in group A** κ values between the two reviewers in group B

method to reduce both radiation and contrast doses is to optimize the selection of tube voltages. Most previous CCTA studies on 64-multislice CT, 128-slice dual-source CT, or 320-row CT used a fixed tube voltage of 100 kVp or 120 kVp. Although diagnostic images could usually be obtained, the mean radiation dose is reported on the order of 1.7–10.4 mSv, with an average of 4.9 mSv [19, 20], with CM dosage between 60 and 90 ml [21]. On the other hand, lower tube voltages produce X-rays with lower average energy photons that are closer to the k-edge of iodine, which is the clinically relevant component of contrast medium, and provide much stronger enhancement effect for iodine. Since in clinical practice the diagnostic performance of CCTA is mainly dependent on adequate enhancement (≥ 250 – 280 HU), as well as acceptable CNR in vessels, which is usually determined collectively by the scanning parameters, reconstruction algorithms, and contrast medium (CM) injection, this stronger enhancement at lower tube voltages may be taken advantage of to reduce the required contrast dose for similar enhancement or to relax the requirement for image noise for similar contrast-to-noise ratio when using lower tube voltages. Historically, the lowest tube voltage has been limited to 80 kVp. However, in recent years, at least two CT manufactures have introduced a 70-kVp tube voltage station with the average photon energy move closer to the k-edge of iodine. Since their introduction, the use of 70-kVp tube voltage has been explored in several clinical applications including in aortic CT angiography [22], cerebral CT angiography

[23], lower extremity CT angiography [24], and high-pitch CCTA [25–28]. Zhang et al [25, 26] have demonstrated that compared with the 80- and 100-kVp settings, the radiation doses of the 70 kVp on a second-generation dual-source CT with 30-mL contrast agent (370 mgI/ml) protocol were reduced by 56% and 75%, respectively. Another similar study by Wang et al [28] reported that prospectively ECG-triggered high-pitch CCTA at 70 kVp with 30 mL contrast agent can reduce radiation dose while maintaining image quality and high diagnostic accuracy. These high-pitch CCTA studies with 70 kVp were all carried out on dual-source CT systems that excluded either patients with heart rates higher than 65 bpm or patients with arrhythmia or heart rate variability more than 30 bpm. To our knowledge, our study was the first study on a 16-cm wide-detector CT system to demonstrate the ability to use 70 kVp for significantly reducing both radiation dose and contrast dose in CCTA. Also, by fully taking advantage of the one heartbeat CCTA capability of the 16-cm wide-detector collimation with 0.28-s rotation speed, we were able to include patients with high heart rate, high heart rate variability, or high arrhythmia (including atrial fibrillation). We found that all cases successfully completed their CCTA and all images obtained were clinically acceptable. Similar to the findings of earlier CCTA studies using the high-pitch, 70-kVp protocol on dual-source CT systems, in our study, we obtained 75.3% reduction in effective radiation dose and 42.4% reduction in contrast dose while maintaining diagnostic image quality, but without limitations on patient heart rate and rhythm. Radiation dose reduction was achieved by setting up a higher noise index in the study group (group A) during scanning. On the other hand, noise in the images was reduced by using the new-generation volume-based adaptive statistical iterative reconstruction (ASiR-V) algorithm. Benz DC et al [29] reported that increasing ASiR-V levels (percentages from 0 to 100%) resulted in significant noise reduction, improved SNR, and better image quality for low-dose CCTA and reconstructions with 100% ASiR-V yielded the best image quality.

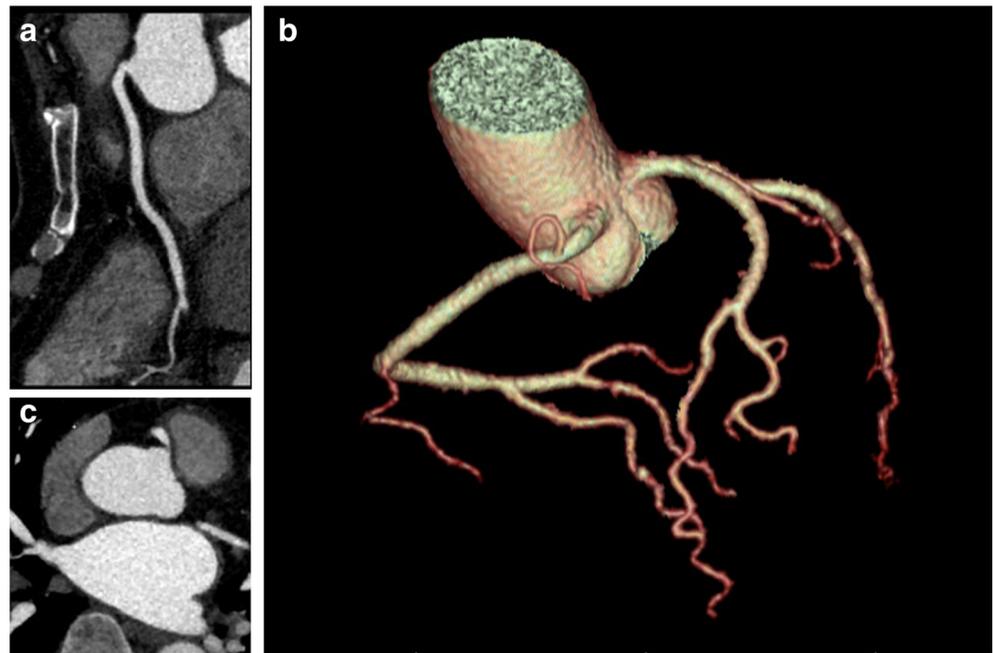
Contrast medium (CM) injection protocol also plays an important role in reducing CM doses. Kok et al [30] systematically investigated how to optimize CM injection parameters at lower peak kilovoltage settings and suggested it may be an optimization option in combining total iodine load (TIL = total

Table 4 Final consensus subjective image quality score distributions in overall image quality and each coronary artery between group A and group B

	Final consensus score distribution (1/2/3/4/5)		
	Group A (n = 30)	Group B (n = 30)	p value [#]
Overall image quality	0/0/3/19/8	0/0/2/20/8	0.847
RCA	0/0/4/19/7	0/0/4/16/10	0.513
LAD	0/0/3/20/7	0/0/3/18/9	0.639
LCX	0/0/5/18/7	0/0/4/17/9	0.541

[#]p values between the two groups for the overall image quality and three major coronary vessels

Fig. 1 70-kVp coronary CT angiography was performed on a 63-year-old with recent-onset atrial fibrillation (AF) suspected of having CAD. **a** Axial image, **b** volume rendering (VR) of the coronary tree image, and **c** curved planar reformat (CPR) image enabled us to evaluate the coronary with clear vessel boundary and without motion artifact

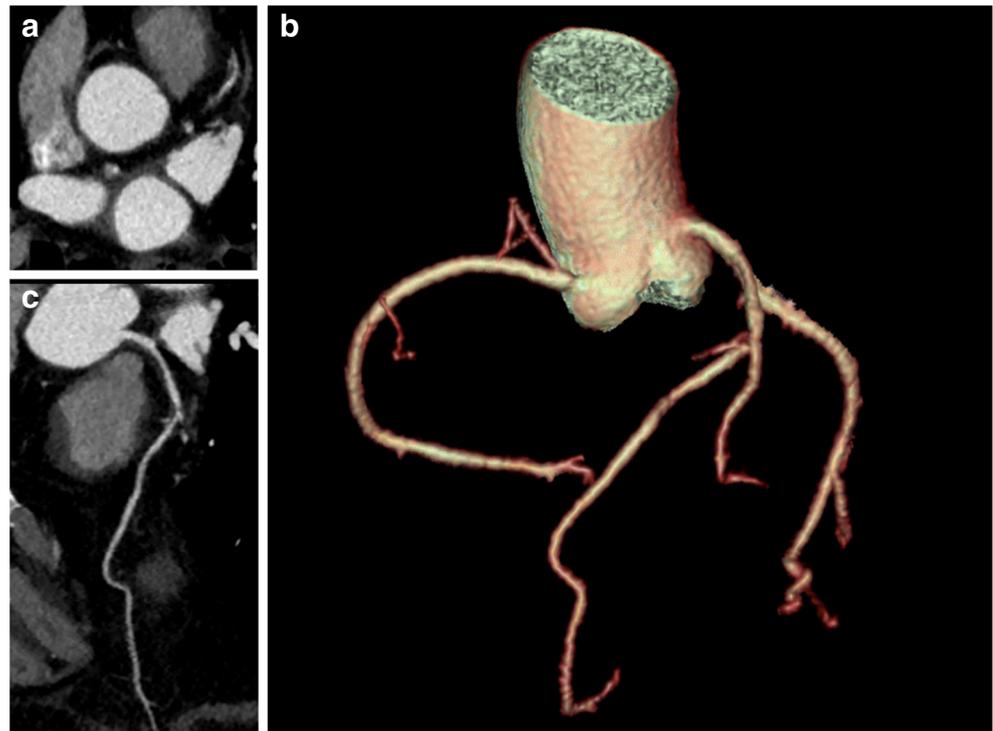


iodine in g I) with iodine delivery rate (IDR = the amount of iodine injected per second [g I/s]) to reduce doses. In this way, CM uniformity can be ensured even when using different CM types. Thus, unlike most previous studies which used a fixed CM dose of 30 ml or 40 ml, in this study, we used a CM injection protocol based on patient weight at a reduced 16 mg I/kg/s contrast dose rate for 9 s of injection time, instead of the conventional contrast injection protocol at a contrast dose rate of 25 mg I/kg/s for 10 s. The 70-kVp group only required an

average amount of 22.46 ml of CM, a mean contrast dose reduction of 42.4%, compared with the 100-kVp group.

Despite the obvious advantage of the much-improved contrast enhancement by using low tube voltages such as the 70 kVp, there are limitations to its use. The first limitation is the need to be able to have sufficient tube current at lower kilovoltage to keep image noise low enough [31], especially for large patients. A second limitation is the reduced dose efficiency for large patients due to the existence of many low-energy photons in the 70-kVp

Fig. 2 100-kVp coronary CT angiography was performed on 66-year-old female with paroxysmal palpitation and chest tightness for 1 year suspected of having CAD. **a** Axial image, **b** volume rendering (VR) of the coronary tree image, and **c** curved planar reformat (CPR) image enabled us to evaluate the coronary with good image quality and without motion artifact



X-ray spectrum. This reduced dose efficiency may cause significant noise increase for large patients when compared with higher tube voltages such as 120 kVp at similar radiation dose. In our study, we limited patients with body mass index (BMI) less than 23 kg/m² as the study population. This BMI criterion was consistent with the one used in the study by Zhang et al [26]

Our study had limitations. First, the study was focused on image quality comparison and no invasive angiography validation was performed. In addition, sample size was relatively small; only 2 patients out of 60 had atrial fibrillation during the scan, which makes the conclusion of our study not enough validated in the subgroup of patients with atrial fibrillation. Third, we did not perform evaluation on patients with larger BMI values. Further investigation with a larger sample size and larger BMI is being carried out.

In conclusion, the prospectively ECG-triggered CCTA using 70 kVp and high-level volume-based adaptive statistical iterative reconstruction (ASiR-V) algorithm on a 16-cm wide-detector CT system provides diagnostic images with substantial reduction in both radiation dose and contrast agent dose compared to the conventional CCTA using 100-kVp tube voltage.

Acknowledgements We gratefully acknowledge Dr. Shen Yun for their technical support in this study.

Funding The authors state that this work has not received any funding.

Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Taiping He.

Conflict of interest The authors of this manuscript declare no conflict of interest exists in the submission of this manuscript.

Statistics and biometry No complex statistical methods were necessary for this paper.

Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Institutional Review Board approval was obtained.

Methodology

- prospective
- randomized controlled trial
- performed at one institution

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