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Image quality and diagnostic value of ultra low-voltage, ultra low-contrast coronary CT angiography

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Abstract

Objective To explore the image quality (IQ) and diagnostic value of 70 kVp turbo high-pitch coronary CT angiography (THP-CCTA) using automated tube voltage selection (ATVS) and 30 mL of low-concentration contrast agent.

Methods Patients who underwent 70 kVp THP-CCTA using ATVS with 30 mL of contrast agent (group A) were prospectively enrolled, and those who underwent conventional CCTA (100/120 kVp, prospective sequential mode with 65–75 mL of contrast agent) (group B) were retrospectively selected for study. IQ was assessed subjectively on a 5-point scale, and diagnostic value was assessed based on invasive coronary angiography as the gold standard. Heart rate (HR), HR fluctuation (HRF), body mass index (BMI), effective radiation dose (ED), and iodine uptake (IU) were recorded.

Results A total of 796 patients (398/398 in groups A/B) were included. Between-group differences in age, gender, BMI, HR, HRF, and IQ values were not significant. The ED/IU values were 0.3 ± 0.1 mSv/9.0 ± 0.0 g and 5.8 ± 1.8 mSv/22.9 ± 1.0 g in groups A and B, respectively ($p < 0.01$). The sensitivity, specificity, positive and negative predictive values, and accuracy of THP-CCTA for the diagnosis of ≥ 50% stenosis were 94.8%, 97.5%, 92.0%, 98.4%, and 96.9% respectively. The mean HR and coronary calcium score were independent predictors of diagnostic image quality, and the best cutoff values were 71.5 bpm and 444.1 respectively.

Conclusion This third-generation dual-source CT imaging modality, a 70-kVp THP-CCTA system using ATVS with 30 mL of low-concentration contrast agent, produces high-quality images with high diagnostic accuracy for significant stenosis, with ultra low ED and IU. This technique was most promising in individuals with an HR < 71.5 bpm and coronary calcium score < 444.1.

Key Points

- *Turbo high-pitch CCTA using 70 kVp via automated tube voltage selection and 30 mL of low-concentration contrast agent is feasible.*
- *This protocol provides high diagnostic accuracy for significant coronary stenosis and reduces radiation doses and iodine uptake significantly.*
- *This protocol was most promising in individuals with an HR < 71.5 bpm and coronary calcium score < 444.1.*

Keywords High-pitch acquisition · Coronary computed tomography angiography · Radiation dosage · Iodine

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Abbreviations

ATVS	Automated tube voltage selection
AUCs	Areas under curves
BMI	Body mass index
DLP	Dose length product
DSCT	Dual-source CT
ED	Effective radiation dose
HR	Heart rate
HRF	HR fluctuation
ICA	Invasive coronary angiography
IQ	Image quality
IU	Iodine uptake
ROC	Receiver operating characteristic
THP-CCTA	Turbo high-pitch coronary CT angiography

Introduction

Noninvasive coronary computed tomography angiography (CCTA) has partially replaced invasive coronary angiography (ICA) in routine clinical practice for the screening and follow-up of patients with coronary heart disease. Recent trials of second-generation dual-source CT (DSCT) systems have demonstrated that a high-pitch scan mode combined with a low tube voltage (80 kVp) can produce high-quality images with high diagnostic value for coronary stenosis, with radiation doses as low as ~1 mSv. These studies indicated that image quality (IQ) and diagnostic value were dependent on heart rate (HR) and heart rate fluctuation (HRF) [1–3].

A third-generation DSCT system has now been introduced; it features increased temporal resolution (66 ms) and tube power, compared with second-generation DSCT. The third-generation DSCT system provides turbo high-pitch (THP) mode allowing for prospective electrocardiography (ECG)-gated CCTA within one heart beats with even lower tube voltage (70 kVp), and marked reduction of the radiation dose, to ~0.3 mSv [4, 5]. The reduced tube voltage increases image contrast and therefore allows a lower dose of contrast medium. IQ and diagnostic capability for significant stenosis, and the factors affecting them have not yet been clarified. Therefore, in accordance with the "as low as reasonably achievable (ALARA)" principle [6], the purpose of this study was to explore IQ and diagnostic value of images produced by 70 kVp TPH-CCTA performed on a third-generation DSCT system, with 30 mL of low-concentration contrast agent, as well as the influencing factors. Noninvasive conventional CCTA and ICA (gold standard) were used as controls.

Materials and methods

Patients

Patients with suspected coronary artery disease were prospectively enrolled from June 2017 to March 2018 to undergo 70 kVp THP-CCTA using automated tube voltage selection (ATVS) and 30 mL of low-concentration (300 mg I/mL) contrast agent (group A), and a matching control group (age and body mass index [BMI]) (group B) was selected retrospectively from a cohort that underwent CCTA using a prospective sequential scanning mode at 100/120 kVp with 65 to 75 mL of contrast agent from August 2015 to September 2017. Data on patient characteristics were recorded and included the following: age, gender, height, weight, blood pressure, and blood test results. Smoking was defined as the consumption of at least 1 cigarette per day over the prior year. The exclusion criteria were as follows: age < 18 years, iodine allergy, pregnant or breast feeding, severe arrhythmia such as tachycardia, atrial fibrillation, acute heart failure, or kidney damage (serum creatinine ≥ 120 μmol/L). This study was approved by the Ethics Committee of the First Affiliated Hospital of Dalian Medical University, and all patients in group A gave written informed consent, and in group B, it was waived by the local ethics committee because all CT examinations were clinically indicated.

CCTA parameters and post-processing

A third-generation Siemens Somatom Force DSCT device was used in the study (Siemens Healthineers). Scanning was conducted from 1 cm below the carina to the inferior border of the diaphragm, using the following parameters: rotational speed 250 ms, detector collimation 2 × 96 × 0.6 mm, temporal resolution 66 ms, slice thickness 0.75 mm, slice interval 0.7 mm. Nonionic iodine contrast medium, 300 mg I/mL (Bayer-Schering) was administered as follows: (1) at a flow rate of 4.0 mL/s to group A patients, with an acquisition phase of 65% (HR < 70 bpm) or 30% (HR ≥ 70 bpm) of the RR interval and (2) at a flow rate of 5.0–5.5 mL/s to group B patients, under a prospective ECG-gated sequential scanning mode with an acquisition phase of 30–80% of the RR interval. The bolus of contrast medium was followed by a 30-to-50-mL saline chaser, at the corresponding flow rate. Images were reconstructed with the use of a model-based iterative algorithm (ADMIRE, strength level 4) with a medium soft-tissue kernel (Bv40). Data acquisition was initiated using the bolus tracking method with a region of interest placed at the center of the ascending aorta and the attenuation threshold set to 100 Hounsfield units. The dose length product (DLP) was automatically recorded by the scanner, and the effective radiation

dose (ED) was calculated as follows: ED = k × DLP, with k = 0.014 mSv/mGy × cm. The iodine uptake (IU) value was calculated as follows: dose of contrast agent (mL) × iodine concentration (mg/mL).

All images were transferred to a dedicated workstation (3D Workplace, Siemens Healthineers) equipped with cardiac post-processing software (Syngo.Via CT Coronary, Siemens Healthineers), and the coronary calcium score was automatically calculated. Curved planar reformation and maximum intensity projections were formulated by the post-processing software. The mean HR and HRF were recorded. The mean HR was assessed before image acquisition and consisted of the mean of 5 measurements, and the HRF was defined as the difference between the maximum and minimum HR values.

IQ score and stenosis assessment

The coronary artery was segmented according to American Heart Association (AHA) 15-segment coronary artery classification criteria [7], and IQ and degree of stenosis in coronary segments with a diameter > 1.5 mm were evaluated by two independent radiologists with more than 10 years of experience, who were double blinded for this study. Any disagreement was resolved by consensus after a combined evaluation that included a third radiologist. IQ was scored on a 5-point scale as follows: 5 = excellent (sharp smooth contours of the vascular wall and no streaking or radiating artifacts), 4 = good (slight irregularities of the contour and few streaks or radiating artifacts), 3 = fair (blurred and irregular contour of the vascular wall and numerous streaks or radiating artifacts), 2 = poor (deformation of the vascular wall and many artifacts), and 1 = very poor (obvious deformation of the vascular wall and extensive artifacts). Images with IQ scores of 3–5 satisfied the requirements for performing diagnostic assessments (Fig. 1). The degree of stenosis was determined as follows: normal (smooth parallel/tapering borders), nonsignificant disease (luminal irregularities or stenosis < 50% diameter stenosis), or significant stenosis (stenosis ≥ 50% diameter stenosis).

ICA and analysis

ICA (AlluraXper FD20; Philips Healthcare) was performed according to standard techniques employing several multiple views. A 6F catheter was advanced into the coronary artery via the femoral artery or the radial artery, and angiography of the right and left coronary arteries was selectively performed in sequence. The degree of stenosis was evaluated using the same method used for CCTA.

Statistical analysis

The data were analyzed by SPSS 21.0 statistical software (SPSS Inc.). Continuous data were expressed as means ± SD, and categorical data were expressed as percentages. The continuous and categorical variables were analyzed by the t test and χ^2 test, respectively. Agreements between the two radiologists or between CCTA and ICA findings were analyzed by the Kappa test. Independent predictors of diagnostic value were identified by a bivariate logistic regression model, and cutoff values, sensitivity, and specificity were determined by analysis using receiver operating characteristic (ROC) curves. $P < 0.05$ indicated statistical significance.

Results

A total of 796 patients were included in the study, 398 in group A and 398 in group B. Group A consisted of 254 men and 144 women, aged 23 to 88 years (64.7 ± 13.4 years). The ED in group A was 0.2 to 0.4 mSv (0.3 ± 0.1 mSv). Group B was comprised of 236 men and 162 women, aged 35 to 83 years

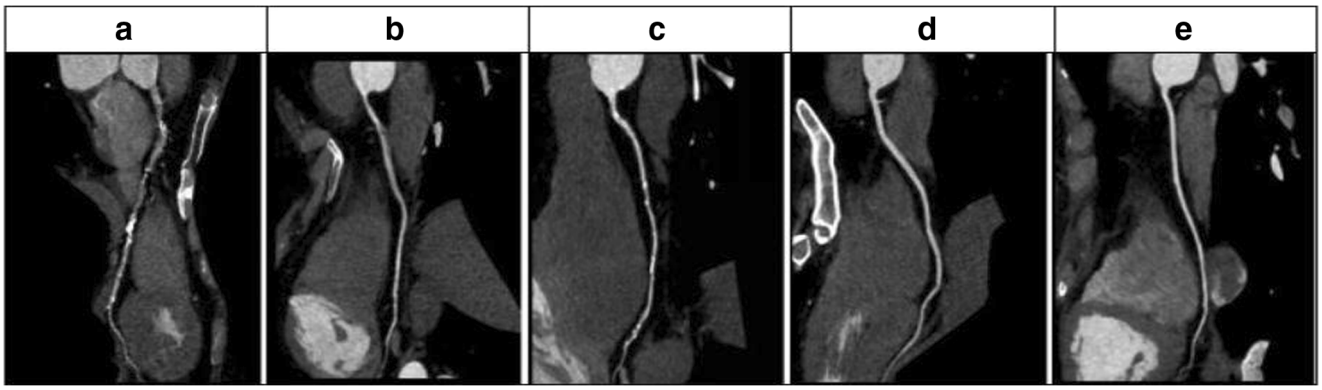

Fig. 1 Curved planar reformations of the right coronary artery showing examples of the 5-point subjective image quality scale for coronary computed tomographic angiography in group A patients, from the lowest to highest score (**a**–**e**). **a** Extremely high noise resulting in a nondiagnostic image with image quality (IQ) score = 1; **b** poor image quality, IQ score = 2; **c** fair image quality, IQ score = 3; **d** good image quality, IQ score = 4; **e** excellent image quality, IQ score = 5

(62.4 ± 11.4 years). The ED was 2.4 to 11.7 mSv (5.8 ± 1.8 mSv). The between-group differences in age, gender, BMI, HR, and HRF were not significant. The DLP, ED, and dose of contrast agent were significantly lower in group A than in group B patients ($p < 0.01$), with the mean ED and IU values decreased by 94.8% and 60.7%, respectively (Table 1).

The agreement between radiologists for IQ scores in both group A and B was good ($K = 0.743$ and $K = 0.785$ respectively; $p < 0.01$). Group A (5,038 segments) showed 680/2220/1837/231/70 segments with respective IQ scores of 5/4/3/2/1, with a mean IQ score of 3.6 ± 0.8; group B (5,321 segments) showed 824/2171/2113/165/48 segments with respective IQ scores of 5/4/3/2/1, with a mean IQ score of 3.7 ± 0.8 ($p > 0.05$). The between-group difference in the number of interpretable segments ($n = 4737$ [94.0%] in group A and 5108 [96.0%] in group B) was not significant.

Patients from each group who also underwent ICA were further subclassified into group A1 (30 cases, 418 segments) and group B1 (58 cases, 803 segments). The K values for diagnostic consistency between CCTA and ICA were 0.929 and 0.956, respectively. With ICA as the reference standard and the coronary segment as the unit, the sensitivity, specificity, positive and negative predictive values, and accuracy of CCTA for coronary stenosis ≥ 50% were 94.8%, 97.5%, 92.0%, 98.4%, and 96.9%, respectively, for group A1 and 97.4%, 98.5%, 95.4%, 99.2%, and 98.3%, respectively, for group B1 patients (Table 2). There were 13 incorrectly diagnosed lesions (8 overestimated and 5 underestimated; 7 in the left anterior descending branch, 3 in the left main coronary artery, and 3 in the right coronary artery) in 6 patients, and 9 of the lesions were identified as mixed plaques with severe calcifications (Figs. 2 and 3). Bivariate logistical regression of group A patients that included BMI, mean HR, HRF, and coronary calcium score identified the mean HR and coronary calcium score as independent predictors of diagnostic value (Table 3). ROC curves for mean HR and coronary calcium score were plotted with correct diagnoses as the positive event. The areas under curves (AUCs) were 0.842 and 0.836, respectively. The best cutoff value for mean HR was 71.5 bpm, which yielded a sensitivity and specificity for diagnostic accuracy of 85.7% and 73.0%, respectively, and the best cutoff value for coronary calcium score was 444.1, which yielded a sensitivity and specificity of 87.5% and 81.0%, respectively (Fig. 4).

Table 1 Patient characteristics, radiation dose, and iodine uptake in both groups

Parameters	Group A	Group B	p
Age (years)	64.7 ± 13.4	62.4 ± 11.4	0.073
Male, n (%)	254 (63.8%)	236 (59.3%)	0.533
BMI (kg/m^2)	24.9 ± 3.0	25.7 ± 3.7	0.067
Heart rate (bpm)	69.3 ± 10.8	67.7 ± 13.9	0.154
Hypertension, n (%)	251 (63.1%)	255 (64.1%)	0.769
Hyperlipidemia, n (%)	124 (31.2%)	113 (28.4%)	0.394
Diabetes, n (%)	34 (8.5%)	30 (7.5%)	0.603
Smoking history, n (%)	80 (20.1%)	98 (24.6%)	0.126
HRF (bpm)	8.5 ± 4.9	8.0 ± 6.3	0.797
DLP (mGy·cm)	23.6 ± 3.1	416.4 ± 2.9	< 0.01
ED (mSv)	0.3 ± 0.1	5.8 ± 1.8	< 0.01
Iodine uptake (g)	9.0 ± 0.0	22.9 ± 1.0	< 0.01

Group A: turbo high-pitch coronary computed tomography angiography mode group; group B: conventional coronary computed tomography angiography mode group

BMI body mass index, *HRF* heart rate fluctuation, *DLP* dose length product, *ED* effective dose

Table 2 Quantitative comparison of the diagnostic value of significant coronary stenosis by THP and conventional CCTA, with coronary segment as the unit and ICA as the standard

CCTA	ICA				Total
	Group A (n)		Group B (n)		
	Positive	Negative	Positive	Negative	
Positive	92	8	187	9	296
Negative	5	313	5	602	925
Total	97	321	192	611	1221

Group A: turbo high-pitch CCTA group; group B: conventional CCTA group; positive: degree of coronary stenosis ≥ 50%; negative: degree of coronary stenosis < 50%

CCTA coronary computed tomography angiography, *ICA* invasive coronary angiography

Discussion

THP-CCTA performed with a third-generation DSCT system using 70 kVp via ATVS, and 30 mL of low-concentration (300 mg I/mL) contrast agent, produced high-quality images of the coronary arteries, with a rate of interpretable images and diagnostic accuracy for significant coronary stenosis of 94.0% and 96.9%, respectively, and radiation doses as low as ~ 0.3 mSv and IU values as low as ~ 9.0 g. HR and coronary calcifications were identified as factors that independently affected diagnostic accuracy, with cutoff values for HR and coronary calcium score of 71.5 bpm and 444.1, respectively.

The ongoing innovations in CT technology and improvements in CT scanners have led to the introduction of various new high-end CT devices into the clinical sphere. This includes the wide detector or DSCT, with development of corresponding CCTA protocols. The radiation dose can be effectively reduced by techniques such as THP, low tube voltage, iterative reconstruction, and low tube current [8–12]. The radiation dose is linearly related to the square of the tube voltage

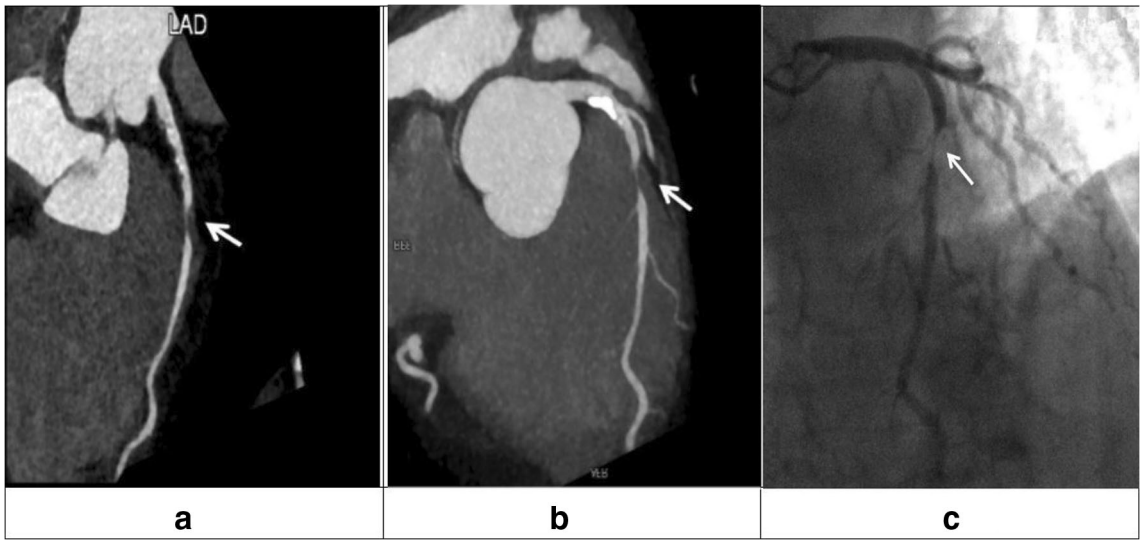

Fig. 2 Coronary stenosis by turbo high-pitch coronary computed tomography angiography and invasive coronary angiography for a 57-year-old man with chest pain (mean heart rate = 62, body mass index = 23.18, effective radiation dose = 0.35). The curved planar reconstruction image in **a** and the maximum intensity projection image in **b** show noncalcified plaques at the proximal segment of the left anterior descending branch and severe lumenal stenosis; invasive coronary angiography (**c**) indicates 90% stenosis of the #6 segment of the left anterior descending branch

and is thus most effectively decreased by reducing the tube voltage. In addition, with a lower tube voltage, the X-ray energy approaches the K-edge energy of iodine and the photoelectric effect improves enhancement. Both concur to reducing the dose of contrast medium. A THP-CCTA scanning protocol that uses 80 kVp has been reliably used for second-generation DSCT, bringing the radiation dose down to ~ 1 mSv [13–17]. However, IQ was altered due to increased noise. In our study, the third-generation DSCT system increased the upper limit of tube current from 500 mA (second generation) to 1300 mA. A higher tube current is guaranteed at the ultra low tube voltage of 70 kVp, and the image noise is greatly reduced by the photon detector combined with the ADMIRE technique. Thus, 70 kVp low tube voltage scanning can be used for CCTA and can further decrease the radiation dose and this technique has become a focus for research [4, 18–20]. However, in previous studies, high doses (45 to 60 mL) of high-concentration contrast agents have been used, and the diagnostic capability of 70 kVp CCTA for significant coronary stenosis has not been further assessed. Zhang et al

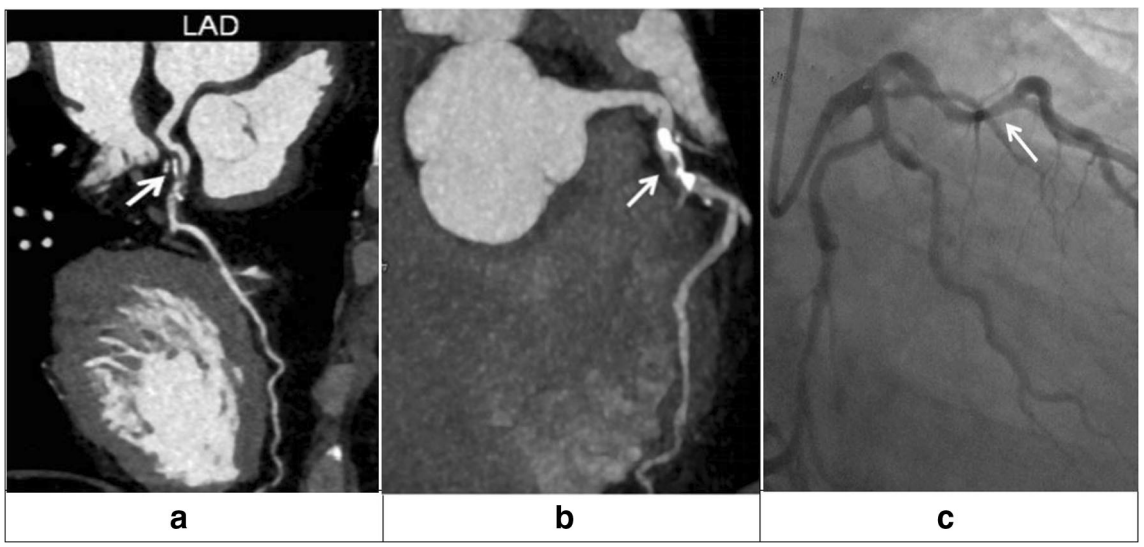

Fig. 3 Turbo high-pitch coronary computed tomography angiography and invasive coronary angiography for a 59-year-old man with chest pain (mean heart rate = 50, body mass index = 26.26, effective radiation dose = 0.37). The curved planar reconstruction image in **a** and the maximum intensity projection image in **b** show calcified plaques in the proximal segment of the left anterior descending branch with severe stenosis, and invasive coronary angiography (**c**) indicates 40% stenosis in the #6 segment of the left anterior descending branch

Table 3 Predictors of diagnostic value of turbo high-pitch coronary computed tomography angiography for significant coronary stenosis by bivariate logistic regression analysis

Influencing factor	*B* value	95% CI	*p*
Body mass index	0.077	0.689–1.692	0.738
Heart rate	− 0.166	0.838–0.947	0.000 (< 0.05)
Heart rate fluctuation	− 0.005	0.954–1.038	0.815
Coronary calcification score	− 0.004	0.689–1.692	0.031 (< 0.05)

[21] and Wang et al [22] have reported trials on THP-CCTA performed by second-generation DSCT systems with 70 kVp tube voltage plus 30 mL of contrast agent. However, the contrast agents had higher concentrations of iodine (370 mg/mL), and the BMI and HR of study participants were strictly limited to ≤ 25 kg/m^2 and ≤ 70 bpm. In this study, we performed THP-CCTA using a third-generation DSCT system with 70 kVp automated tube voltage and 30 mL of low-concentration (300 mg I/mL) contrast agent. With the coronary segment as a unit, the rate of produced interpretable images was 94.0%, which was similar to that obtained by conventional CCTA, but the radiation and contrast doses were significantly reduced, by 94.8% and 60.7%, respectively. Moreover, we did not administer agents for controlling the HRs of patients, and we selected patients with BMIs that were suitable for 70 kVp THP-CCTA examinations using ATVS. The BMI and HR were not strictly limited, although neither of the mean values of 24.9 ± 3.0 kg/m^2 and 69.3 ± 10.8 bpm was significantly different from the values of study patients who had undergone conventional CCTA. Compared with the BMIs (22.1 to 22.5 kg/m^2) and mean HRs (61.5 to 62.3 bpm) of the study patients of Zhang et al [21] and Wang et al [22], the limits of the BMIs and HRs of our study patients were obviously relaxed to expand the inclusion criteria for our experimental scanning protocol. For second-generation DSCT, the strict limitations on HR and BMI might be required, in addition to high-concentration contrast agents, as a relevant high tube current cannot be guaranteed for 70 kVp. The temporal resolution obtained by second-generation DSCT systems is also lower than that obtained by third-generation DSCT systems. In addition, the ATVS method offers reported advantages, including convenience, high accuracy, and an approximately 30% decrease in the radiation dose compared to manual, BMI-based tube voltage adjustment, without significant difference in image noise and with a partial increase in the signal-to-noise ratio [23]. Manual, BMI-based tube voltage adjustment relies on the overall average constitutional characteristics of the patient, but coronary artery scanning is concentrated on the chest, and the somatotype of the chest is not completely consistent with the BMI of the patient [23, 24]. In our study, THP-CCTA with ultra low ATVS tube voltage and ultra low-contrast agent concentration yielded diagnostic accuracy and negative predictive values for significant coronary stenosis of 96.9% and 98.4%, respectively. These results were basically similar to those obtained by a conventional CCTA scanning mode. The conventional CCTA scan mode used for our B1 subgroup of patients showed a diagnostic accuracy and negative predictive value for significant coronary stenosis of 98.3% and 99.2%, respectively. Furthermore, our study showed there was high degree of diagnostic consistency between THP-CCTA and the gold-standard ICA ($K = 0.929$).

We performed a stepwise regression analysis to identify factors that affected the diagnostic value of 70 kVp low-contrast

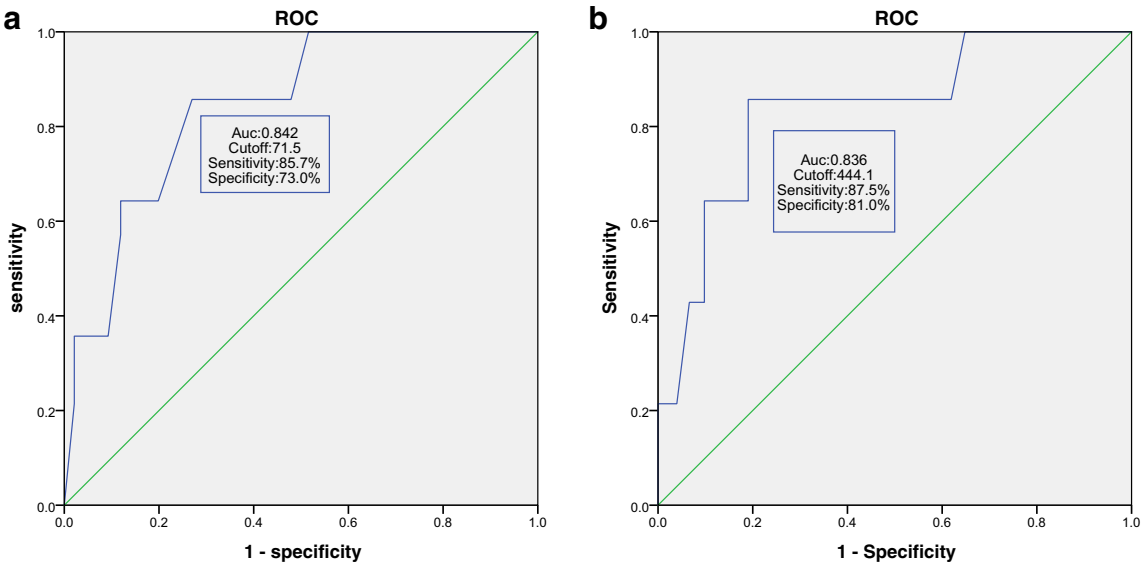

Fig. 4 ROC curves for mean HR (**a**) and coronary calcium score (**b**) were plotted with correct diagnoses obtained by the THP-CCTA mode as the positive event. The AUCs of mean HR and coronary calcium score were 0.842 and 0.836, respectively. HR, heart rate; ROC curve, receiver operating characteristic curve; AUC, area under the curve; THP-CCTA, turbo high-pitch coronary computed tomographic angiography

THP-CCTA and found that HR and coronary calcium score were independent predictors of diagnostic value. These results might be accounted for by the fact that *Z*-axis scanning of the entire heart still takes 250 ms with the third-generation DSCT system in the THP scanning mode. In patients with elevated HR, the images are probably acquired at the next PR interval, and even the QRS wave causes an artifact because of a markedly shortened diastole. Moreover, in addition to HR, our study showed that severe coronary calcification was an important factor that affected diagnostic accuracy for significant stenosis. Most of the misdiagnosed lesions in our study were associated with extensive calcification artifacts, possibly because the calcifications were weakly penetrated by the 70 kVp tube voltage, leading to more obvious beam-hardening artifacts. In addition, a too-high pitch widens the slice sensitivity curve and reduces the spatial resolution of the *Z*-axis images, which would have further caused a stronger volume effect of calcification compared to the conventional scanning mode. Therefore, these artifacts affected the diagnostic value of 70 kVp low-contrast THP-CCTA, and this mode is not suitable for patients with the elevated HR and severe coronary calcification that calcification score scanning indicates.

We also plotted ROC curves for HR and coronary calcium score with correct diagnoses as the positive event and found that the best diagnostic value was achieved with cutoff values of 71.5 for HR and 444.1 for coronary calcium score. The radiation and contrast agent doses were decreased to 0.3 mSv and 9.0 g, respectively. Noble et al [1] and Achenbach et al [2] have recommended that the HR should be controlled at ≤ 60 bpm during THP-CCTA performed by a second-generation DSCT system. Noble et al [1] also mentioned that if the HR was controlled at ≤ 60 bpm, better IQ was achieved with an HRF of < 3. Ochs et al [20] were able to increase the upper limit of the HR to 65 bpm by performing THP-CCTA on a third-generation DSCT system, and others have recently reported that satisfactory images could be obtained at higher HRs if the exposure phase was changed appropriately [25, 26]. They reported that THP-CCTA with exposure duration of 20 to 30% of the RR interval in patients with an increased HR (> 65 bpm) produced an image quality similar to that obtained by traditional CCTA. However, further studies are required to verify the clinical feasibility of these techniques, because the sample sizes were small. In addition to elevated HR, Ochs et al [20] also recommended that THP-CCTA should not be performed in patients with a coronary calcium score > 600, as the image quality decreases above the limit. Therefore, when calcification score scanning indicates extensive calcification of the coronary arteries (coronary calcium score of > 444.1) or a patient has an increased HR (HR > 71.5 bmp), conventional CCTA or ICA instead of THP-CCTA should be performed to evaluate coronary artery stenosis in these patients.

This study has limitations. All of the patients undergoing THP-CCTA received 30 mL of contrast medium, and the dose was not further reduced for patients with a low BMI. In addition, this study was a single-center study, and the sample size was small, especially for the subgroups undergoing ICA. A subsequent study will be conducted with a larger patient population drawn from multiple centers, and the clinical applicability will be further validated by adjusting the contrast dose according to BMI. Last, we selected participants who underwent a 70-kVp examination (ATVS), which was suitable for more patients than manual-selection BMI-based tube voltage adjustment, but not suitable for all of the patients.

In summary, THP-CCTA performed with a third-generation DSCT system using 70 kVp via ATVS and 30 mL low-concentration contrast agent, produced interpretable images with high diagnostic accuracy for significant coronary stenosis, and the ED and IU were ultra low. In particular, this technique is applicable for evaluation of suspected coronary artery disease in patients with an HR < 71.5 bpm and coronary calcium score < 444.1.

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Compliance with ethical standards

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Conflict of interest The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

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
- case-control study
- performed at one institution

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