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Performance of dual-source CT with high pitch spiral mode for coronary stent patency compared with invasive coronary angiography

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Abstract

Objective To investigate the performance of dual-source computed tomography (DSCT) using high-pitch spiral (HPS) mode for coronary stents patency. **Methods** We conducted a prospective study on 120 patients with 260 previous stents implanted due to recurred suspicious symptoms of angina scheduled for invasive coronary angiography (ICA), while DSCT were conducted using HPS mode. **Results** There was no significant impact of age, body mass index or heat rate (HR) on image quality ($P > 0.05$), while HR variability had a slight impact on that ($P < 0.05$). Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) of DSCT in detection of in-stent restenosis (ISR) based per-patient were 92.3%, 96.7%, 88.9%, and 97.8%, respectively. And those based per-stent were 87%, 96.8%, 83.3%, and 97.7% with un-assessment stents, 97.4%, 99.5%, 97.4%, and 99.5% without un-assessment stents. There was significant difference on sensitivity, specificity, PPV and NPV between diameter ≥ 3.0 mm group (93.3%, 97.9%, 87.5%, and 98.9%) and diameter < 3.0 mm group (80%, 93.3%, 80.0%, and 93.3%) ($P < 0.05$), and that between stent number ≥ 3 group (82.3%, 77.8%, 66.7%, and 60%) with < 3 group (97.3%, 80%, 96.5%, and 75%). The effective dose of DSCT (1.4 ± 0.5 mSv) is significantly less than that by invasive coronary angiography [4.0 ± 0.8 mSv ($P < 0.01$)]. **Conclusion** DSCT using HPS mode provides good diagnostic performance on stent patency with lower effective dose in patients with HR < 65 beats/min.

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Keywords: Coronary angiography; High-pitch spiral mode; Percutaneous coronary intervention; Stent

1 Introduction

Percutaneous coronary intervention (PCI) is the treatment of choice for patients with coronary artery disease (CAD). Minimally invasive coronary artery stent procedures with either bare metal or drug eluting stents (BMS, DES) predominate myocardial revascularization therapies over bypass surgery. The use of DES has reduced the occurrence of in-stent restenosis (ISR) from about 20% to 30% in BMS to less than 10% in DES.[1,2] Since ISR is a major complication of coronary intervention procedures with considerable morbidity and mortality, an early diagnosis is of clinical significance to prevent secondary myocardial infarction, leading to improving long term prognosis.[3] Conventional invasive coronary angiography (ICA) was widely used in clinical to detect the in-stent restenosis as follow-up since it allowed direct visualization of the vessel lumen with both high spatial and temporal resolution.[4,5] However, it is an invasive procedure with severe complications sometimes and negative findings in symptomatic post-stenting patients are usual. Thus, an alternative non-invasive imaging modality to ICA may markedly reduce the number of negative ICA as well as undesired complications and was the agent to develop in clinical practice.

Recently, with the advent of 128-slice dual-source CT (DSCT) system (Definition Flash, Siemens Healthcare, Forchheim, Germany), the prospective ECG-synchronized high-pitch spiral (HPS) mode applied to coronary CT angiography could reduce radiation dose while keeping or increasing the image quality.[6] These reports demonstrated that HPS mode was a promising method for assessing native coronary arteries with lower radiation dose; however, the diagnostic accuracy of this new approach to evaluate coronary stents *in vivo* remained unknown. The purpose of our study was to evaluate the accuracy of high-pitch 128-slice dual-source CT for the assessment of coronary stents compared with ICA.

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2 Methods

2.1 Patients population

One hundred and twenty patients with previous stent implantation who were scheduled for follow-up ICA due to recurred suspicious symptoms of angina with positive findings at stress testing were prospectively enrolled between September 2012 and October 2013. Exclusion criteria were as follows: known allergy to contrast agent, renal failure (serum creatinine > 1.5 mg/dL), arrhythmia, heat rate (HR) < 65 beats/min could not be achieved after the administration of β-blockers. All patients underwent both DSCT and conventional ICA within seven days. The patients gave their written informed consent before DSCT and ICA examinations, and the study protocol was approved by the hospital ethics committee.

2.2 DSCT scanning protocol

All examinations were performed on DSCT scanner (Definition Flash, Siemens Healthcare, Forchheim, Germany). Data acquisition was performed with a detector collimation of 2 mm × 64 mm × 0.6 mm, Z-axis flying focus technique and gantry rotation of 280 ms. Patients with body mass index (BMI) ≥ 25 mg/m^2 were examined with a tube voltage of 120 kVp, whereas patients with BMI < 25 mg/m^2 with a tube voltage of 100 kVp. The tube current modulation was applied at full for 60%–80% of R-R interval. Each tube provided a maximum of 430 mAs/rotation.

Three minutes before DSCT, 0.5 mg of sub-lingual nitroglycerin spray (Nitroglycerin Aerosol; Jewim Pharma, Shandong, China) was administered. The administration of oral β-blockers or intravenous injection of esmolol were given to achieve HR < 65 beats/min. Contrast agent (Ultravist 370, Schering, Berlin, Germany) was injected into the antecubital vein at a flow rate of 5.0 mL/s, followed by a saline chaser (40 mL). The contrast volume was calculated with the following equation: estimated scan time + scan delay (13 s). The contrast volume varied between 50 and 80 mL depending on the scan time, which in turn varied between 5 s and 13 s. The bolus-tracking technique was used to synchronize the start of the scan with the arrival of contrast agent in the coronary arteries. One circular region-of-interest (ROI) was positioned in the ascending aorta and the scan was automatically started when a threshold of +100 Hounsfield Units was reached inside the ROI. Flash mode was with a pitch factor of 3.4 and prospectively ECG-synchronized. Sixty percent of the R-R interval was set for the start of the data acquisition window.

2.3 DSCT image analysis

All images were transferred to a dedicated multi-modality workplace (MMWP 2011A, Siemens) for further analysis. Contrast enhanced CT images were reconstructed with B26f kernel, slice thickness of 0.75 mm, an increment of 0.5 mm for visualization of native arteries and with B46f kernel, slice thickness of 0.6 mm, an increment of 0.4 mm for visualization of stents. Two independent radiologists with five years of cardiac CT experience blinded to the results of ICA evaluated the CT images quality. Disagreements were resolved by consensus, which was achieved in all discordant cases. Inter-observer agreement was calculated, and CT images analysis was conducted in two steps. Firstly, using both original axial images and curved multiplanar reformations concurrently, the stent image quality of DSCT was evaluated on a scale from 1 (good image quality, no artifacts affecting evaluation of stent), 2 (moderate image quality, mild to moderate artifacts, blurring but acceptable for clinical diagnosis), to 3 (poor image quality, unassessment with severe artifacts making stent evaluation impossible) according to the criteria used for assessment as showed in Figure 1. In-stent restenosis was defined as diameter of the stenosis ≥ 50% anywhere within the stent or within the 5 mm segments proximal or distal the stent margins. Stent patency was defined as diameter of the stenosis < 50%. All uninterpretable stents (including stents with image quality scale equal to 3 and image quality ≤ 2 but with stents less than 3 mm in diameter resulting lumen not visible) were considered as to have restenosis. Secondly, the noise of the images reconstructed with B26f and B46f respectively was measured in the subcutaneous fat of the ventral aspect of the thorax. Image noise was defined as the standard deviation of the CT attenuation within the region of interest, which was set to 12 pixels.

2.4 ICA

ICA was performed on all patients with standardized projections within one week after DSCT examinations. One experienced cardiologist (10 years of angiographic experience) was blinded to the results of DSCT analyzed all angiographic data using quantitative ICA software (QAngio XA 7.2.24, Medis Medical Imaging systems, BV, Leiden, the Netherlands). Angiographic coronary in-stent restenosis was defined as diameter of the stenosis ≥ 50% anywhere within the stent or within the 5 mm segments proximal or distal the stent margins. The catheter calibration technique was used to measure the length of stent margins. ICA was taken as golden standard, Sensitivity, specificity, positive and negative predictive values and accuracy of DSCT in detection of in-stent restenosis based per-stent and different stent diameter was carried out.

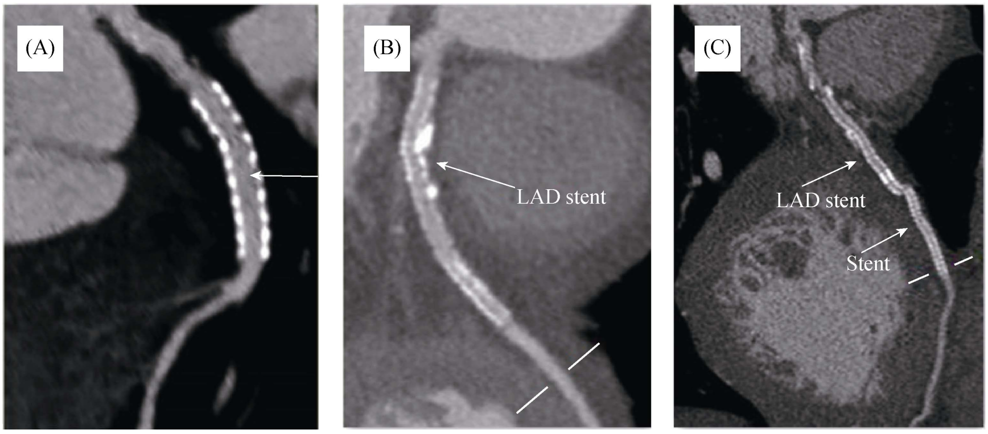

Figure 1. Image quality on a three-point grading scale. (A): Good image quality, no artifacts affecting evaluation of stent with a score of 1; (B): moderate image quality, mild to moderate artifacts, blurring but acceptable for clinical diagnosis with a score of 2; and (C) poor image quality, uninterruptable with severe artifacts making stent evaluation impossible with a score of 3.

2.5 Radiation dose

Scanning range, dose-length product (DLP) and volume CT dose index were obtained from the DSCT scan protocol. Effective radiation dose was calculated as DLP multiplied by a conversion coefficient for the heart (K = 0.017 mSv/mGy per centimeter) according to the Commission of the European Community's Guidelines on quality criteria for CT.[7] For ICA, we calculated effective dose in men and women by a conversion factor (K = 0.10 mGy × cm^2) for lateral and post-eroanterior radiation exposure in the chest area.[8]

2.6 Statistical analysis

Mean ± SD were calculated for all continuous variables. Counts and percentages were calculated for all categorical variables. K statistics were performed for inter-observer agreement of the image quality assessments. The relationship between age, BMI, HR, HR variability and image quality was analyzed using Pearson correlation coefficients. Student *t* test was used to test differences in continuous variables between the two groups. The diagnostic performance between the two groups was compared using the pairwise McNemar's test. A probability value of $P < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS version 11.5 software (SPSS Inc., ChiCAo, IL).

3 Results

3.1 Patients

A total of 260 stents were implanted in 120 patients. If two stents were implanted with an overlap, they were considered as one unless they were of different diameter or type. The number of stents employed varied from one to seven per patient (75% of patients had one stent, 15% of patients had two stents, 10% of patients had 3–7 stents). The diameter and length of stents were acquired from the report of PCI. The mean diameter was 3.41 ± 0.50 mm (range 2.25–4.5 mm) and mean length was 18.3 ± 7.5 mm (range10–53 mm). The general clinical information of the patients was shown in Table 1. More details of stent characteristics are listed in Table 2.

3.2 Image quality of DSCT

Inter-observer agreement for stent image quality was good (K = 0.70). Initial agreement between the two observers was achieved for 244 (93.8%) stents, while consensus reading was required for the remaining 16 (6.2%) stents. One hundred and sixty stents were graded as scale 1 and 96 stents were graded as scale 2 concerning image quality. Four stents was un-assessed and graded as scale 3. The mean image quality scores in DSCT were 1.4 ± 0.5. There was no significant impact of age, BMI or HR on image

Table 1. Clinical information of patients.

Age, yrs	60.2 ± 11.4
Male	86 (71.7%)
HR, beats/min	60.4 ± 6.4
HR variability	4.1 ± 1.8
Risk factors	
Hypercholesterolemia	56 (46.7%)
Diabetes	31 (25.8%)
Current smoking	25 (20.8%)
Hypertension	78 (65%)
History of MI	30 (25%)

Data are presented as mean ± SD or *n* (%). HR: heart rate; MI: myocardial infarction.

Table 2. Stent characteristics.

Diameter	
< 3.0 mm	40 (15.4%)
≥ 3.0 mm	220 (84.6%)
Length	
< 15 mm	34 (13.1%)
16–18 mm	128 (49.2%)
>18 mm	98 (37.7%)
Location	
LM	5 (1.9%)
LAD	115 (44.2%)
LCX	74 (28.5%)
RCA	42 (16.2%)
Multi-vessel	24 (9.2%)
Stent type	
BMS	25 (9.6%)
DES	235 (90.4%)

Data are presented as *n* (%). BMS: bare metal stents; DES: drug eluting stents; LAD: left anterior descending; LCX: left circumflex; LM: left main; RCA: right coronary artery.

quality ($P > 0.05$), while HR variability had a slight impact on image quality ($P < 0.05$, Table 3).

The noise of the images reconstructed with the soft B26f kernel measured in the subcutaneous fat in DSCT was 14.5 ± 4.6 HU, and that reconstructed with B46f kernel was 36.2 ± 8.8 HU. The noise of the images reconstructed with the B46f kernel was significantly increased than that of reconstructed with the soft B26f ($P < 0.05$).

3.3 Diagnostic performance

Inter-observer agreement for stent image patency of DSCT was good (K = 0.76). Initial agreement between the two observers was achieved for 248 (95.4%) stents, while consensus reading was required for the remaining 12 (4.6%) stents. There were 40 stents with restenosis diagnosed by ICA and 42 stents with restenosis diagnosed by DSCT. Figures 2–4 were three typical examples of showing good coherence of DSCT and ICA for coronary stent patency.

Table 3. Data of image quality in DSCT.

Image noise (B26f)	14.5 ± 4.6
Image noise (B46f)	36.2 ± 8.8*
Image quality scores	1.4 ± 0.5
Influence factors	(γ/P)
Age	0.017/0.89
BMI	−0.056/0.67
HR	0.03/0.56
HR variability	0.04/0.02*

**P* < 0.05. BMI: body mass index; DSCT: dual-source computed tomography; HR: heart rate.

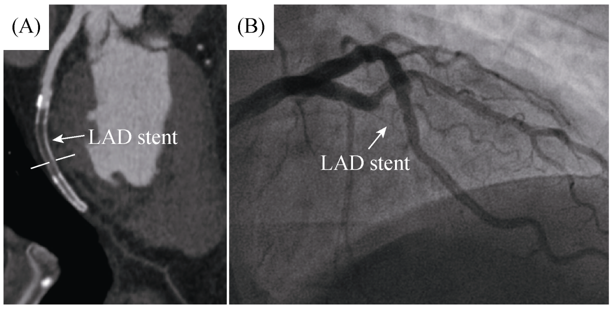

Figure 2. Image with a 52-year-old male of DSCT in HPS group. (A): Curved multi-planar reformatted CT image showed no contrast enhanced in LAD; (B): ICA showed total occlusion in the stent. DSCT: dual-source computed tomography; HPS: high-pitch spiral; ICA: invasive coronary angiography; LAD: left anterior descending.

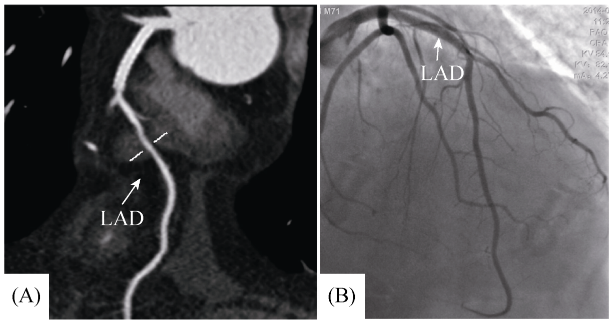

Figure 3. Image with a 65-year-old male of DSCT in HPS group. (A): Curved multi-planar reformatted CT image showed stent patency in LAD; and (B): ICA also showed stent patency in LAD. DSCT: dual-source computed tomography; HPS: high-pitch spiral; ICA: invasive coronary angiography; LAD: left anterior descending.

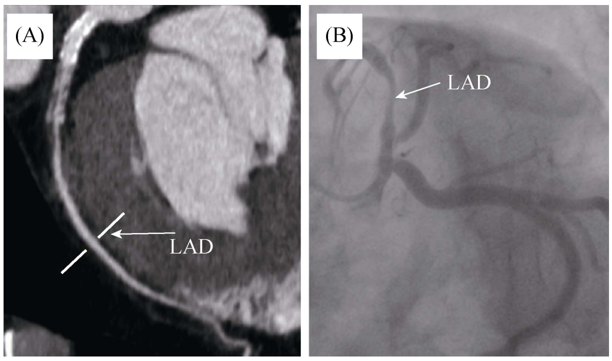

Figure 4. Image with a 70-year-old male of DSCT in HPS group. (A): Curved multi-planar reformatted CT image showed stent restenosis in LAD; (B): ICA also showed luminal stenosis about 80% in LAD. DSCT: dual-source computed tomography; HPS: high-pitch spiral; ICA: invasive coronary angiography; LAD: left anterior descending.

Sensitivity, specificity, PPV and NPV was significant difference between different stent diameter groups and between with/without unassessment stent groups (Table 4).

Table 4. Diagnostic accuracy of DSCT in detection of stent patency.

	Sensitivity	Specificity	PPV	NPV	Accuracy
Per-patient based analysis	92.3%	96.7%	88.9%	97.8%	95%
Per-stent based analysis					
With unassessment stent (n = 260)*	87%	96.8%	83.3%	97.7%	95.4%
Without unassessment stent (n = 256)	97.4%	99.5%	97.4%	99.5%	99.2%
Stent diameter					
< 3.0 mm (n = 40)*	80%	93.3%	80%	93.3%	90%
≥ 3.0 mm (n = 220)	93.3%	97.9%	87.5%	98.9%	97.3%
Stent number					
< 3 stents (n = 236) *	97.3%	80%	96.5%	75%	95.8%
≥ 3 stents (n = 26)	82.3%	77.8%	66.7%	60%	61.5%

*P < 0.05. DSCT: dual-source computed tomography; NPV: negative predictive value; PPV: positive predictive value.

3.4 Radiation dose

The CT dose index and DLP and of every patient were generated from scan protocols automatically and the radiation dose was carried out. The average effective radiation dose of DSCT (1.4 ± 0.5 mSv) was significantly lower than that of ICA (4.0 ± 0.8 mSv, P < 0.01).

4 Discussion

Multi-slice computed tomography angiography (MSCT) had been established as an effective method for the detection of native coronary artery diseases with high negative predictive value.[9–11] However, stent imaging still remained to be a challenge for MSCT. The image quality of coronary stent was not only influenced by the cardiac motion, but also by the metal composition of the stent implanted. The presence of metal within the coronary stent can lead to high-density artifacts, commonly defined as blooming artifacts, subsequently obscuring considerable parts of the stent lumen. This was confirmed by earlier MSCT scanners such as 16-slice CT, with the stent lumen being virtually invisible.[12,13] With the increased slice numbers such as 64-slice, especially DSCT scanners, the improved visualization led to the increased diagnostic accuracy on coronary artery disease and stents imaging had been reported.[14,15]

However, the radiation dose in retrospective ECG-gated coronary CT angiography was still a matter of continual concern.[16] Hence, MSCT had not been accepted for follow-up of coronary stents according to clinical guideline. Effort had been put to reduce the radiation dose. With the advent of 128-slice DSCT, the prospectively HPS ECG-synchronized acquisition mode was introduced. By applying a high pitch factor of 3.4, the fast table movement and faster volume coverage in the Z-axis images made the whole heart datasets acquired in on cardiac cycle, in the meanwhile, the radiation dose was < 1 mSv. Since the gantry rotation time of 128-slice DSCT was 0.28 s, the temporal resolution could be achieved to 75 ms.

Previous phantom studies on coronary artery stent imaging with 128-slice DSCT had found that HPS mode provided the same image quality on coronary stents with less radiation dose in comparison with lower pitch spiral mode *in vitro*.[17,18] There is lack of study *in vivo* on coronary artery stent patency using HPS mode. Therefore, we evaluated the diagnostic accuracy of DSCT with HPS mode in the assessment of coronary artery stent patency compared with ICA in this study. To the best of our knowledge, this was the study with largest number of stents *in vivo* to demonstrate the diagnostic accuracy of DSCT with HPS mode in the assessment of coronary artery stent patency in comparison with ICA as gold standard.

Imaging quality is the key to achieve good diagnostic accuracy. The influential factors of imaging quality were analyzed in our studies and the HR variability was shown to have a slight impact on image quality. In contrary, age, BMI or HR had no significant impact on image quality. Since the best acquisition time of 60% R-R interval in cardiac cycle with HPS mode relied on the stability of five heart beat before data acquisition, in case the five HR before data acquisition was not stable and the variability of HR was increased, the acquisition time would be changed from the best diastolic phase for coronary analysis, which may cause the degraded image quality. The acquisition time (the best diastolic phase) of R-R interval of cardiac cycle in single heart beat with HPS mode must be pre-set. In this study, the acquisition starting time was set at 60% R-R interval of cardiac cycle since the best diastolic phase of regular HR < 65 beats/min was usually at 60% R-R interval, and patients with HR > 65 beats/min after the administration of β-blockers or intravenous injection of esmolol had been ruled out. Therefore, it was very important to keep the lower HR variability in DSCT scan with HPS mode by our experience. Stolzmann, *et al.*,[19] had also confirmed that the average HR and controlled HR variability to be a significant predictor of image quality in high-pitch coronary CT angiography. At a HR frequency ≤ 63 beats/min, 91% of high-pitch coronary CT angiography studies will be of diagnostic image quality. However, a recent study using HPS mode of DSCT showed that HR variability was not significantly related to image quality of coronary CT angiography.[20,21] This is might be explained by the different population. Thus, future studies investigating the impact of HR variability on image quality are warranted.

Both *in vivo* and *in vitro* studies in DSCT using former lower pitch spiral mode had shown significantly good results in visualization of the stent lumen and in-stent restenosis than does single source 64-MSCT. The diagnostic accuracy of DSCT in coronary stent patency evaluation using former lower pitch spiral mode in comparison with ICA was also confirmed by previous studies.[22,23] In our study, the diagnostic accuracy of coronary in-stent restenosis in DSCT using HPS mode was perfect, which was in line with the studies exploring the HPS mode for coronary stent *in vitro*. Moreover, the radiation dose using HPS mode was achieved more than 50% lower than that using former lower pitch spiral mode that had been reported by former studies, ever lower than ICA in our study.

Based on the above mentioned finding of our study, groups of stents with diameter ≥ 3 mm, stent numbers < 3 and per-stent based analysis without un-assessment stent had better diagnostic performance for ISR. Many former studies also reported that stents with nominal diameter ≥ 3 mm and with less stents had best image quality scores, lumen visibility and excellent diagnostic performance comparing to ICA.[24,25] This can be explained partly by image quality caused by artifacts, which include stent-related artifacts and patient-related artifacts. The key for a successful coronary CT scanning and achieved excellent diagnostic accuracy is to reduce those artifacts as much as we can. For stent-related artifacts, stent diameter is the most important factor affecting image quality. Moreover, stent type, including different metal material, strut thickness and cell design, affect the image quality. In our experience, proper convolution kernel (B46) of reconstruction can effectively reduce beam hardening artifacts, which is major type of artifact that complicated the imaging of coronary stents. Hence, pair images of two reconstruction kernels (B26, B46) shall be routinely obtained for delineation of both soft tissue structures (vessel wall, vessel lumen) and objects next to high-density obstacles (stent lumen). For patient-related artifacts, explanation of the examination and good training of breath-holding are the initial steps to ensure good image quality. In addition, HR shall be controlled with administration of β-blocker. Especially, for HPS mode, the stable HR control is more important that for lower pitch spiral mode. Fewer studies focused on the influential factors of total stent numbers for diagnostic performance. In this study, we found that more than three stents decrease the diagnostic performance. It is probable been explained that at least two stents were overlapped in cases of more than three stents and overlapping stent mental structure could effectively enhance beam hardening artifacts, which is the major type of artifact that complicates the imaging of coronary stents. Even so, we still considered that the samples of more than three stents were fewer in this study, and we would deeply study about the stent numbers on diagnostic performance with large samples in future research.

There were several limitations in our study. First, the image quality scores were subjective which may lead to bias existed. However, a good K value indicated good inter-observer agreement and the judgment of stent patency were coherent with ICA. Second, except stent diameter, the in-stent lumen assessability was also influenced strongly by stent thickness, stent material, and design, this part was not included in our study. More studies *in vivo* have to be carried out to report the influence of above mentioned individual factors on diagnostic accuracy of ISR with DSCT using HPS mode. Third, the patients with HR > 65 beats/min had been ruled out. Future studies should be performed in DSCT using HPS mode without HR control. Fourth, some novel techniques such as iterative reconstruction algorithm on the influence to stent image quality and radiation dose had not been addressed in this study. Finally, the data in this study were derived from DSCT, hindering transferability to single-source CT.

In summary, our study is the study with largest number of stents *in vivo* to demonstrate the diagnostic accuracy of DSCT with HPS mode in the assessment of coronary artery stent patency in comparison with ICA as gold standard. Moreover, DSCT using HPS mode provides good diagnostic accuracy on coronary stent patency, especially for stents with a diameter ≥ 3.0 mm, with lower effective dose in patients with HR lower than 65 beat/min compared with ICA.

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