

In vivo evaluation of stent patency by 64-slice multidetector CT coronary angiography: shall we do it or not?

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Abstract The diagnostic performance of in-stent restenosis (ISR) by 64-slice multidetector CT coronary angiography (CTCA) has been reported to be influenced by multiple factors. We evaluated individual factors (stent diameter, material and strut thickness) and therefore determined the proper population for follow-up by using this modality. A total of 171 stents were evaluated in 83 consecutive patients with stents imaged with CTCA and conventional coronary angiography. The stent diameter ranged from 2.25 mm to 4.5 mm. 2 models of stainless steel (Taxus Liberte (Boston Scientific, US), 56 stents and Cypher Select (Cordis, US), 34 stents) and 2 models of cobalt alloy (Endeavor (Medtronic, US), 33 stents and Firebird2 (MicroPort, China), 48 stents) were included. By comparing to conventional coronary angiography, the image quality and diagnostic accuracy for ISR were evaluated. The image quality of Taxus, Endeavor and Firebird are markedly better than Cypher in large caliber group (≥ 3.0 mm) ($P < 0.001$). Except for Cypher, all other stents with diameter ≥ 3.0 mm

showed excellent diagnostic accuracy (sensitivity 100%, specificity 94.4–96% whereas stents with diameter < 3.0 mm had poor diagnostic accuracy (sensitivity 100%, specificity 33.3–70%). Cypher is the stent with thickest strut in our study, and showed reduced image quality and diagnostic accuracy in all stent size, due to large number of unassessable stents. Among 16 binary ISR, 12 lesions were correctly diagnosed by CTCA while the other 4 lesions were unassessable. The main reason for low specificity in small caliber group is the large number of unassessable stents. CTCA has high diagnostic accuracy to identify ISR in selected stents with a diameter of ≥ 3.0 mm.

Keywords Computed tomography · Coronary artery disease · Angiography · Stent

Introduction

Coronary artery stenting is currently the predominant strategy of myocardial revascularization in patients with obstructive coronary artery disease [1, 2]. Even with the wide application of drug-eluting stent (DES), in-stent restenosis (ISR) and stent occlusion (SO) remains the major complication of this procedure [3, 4]. Early detection of ISR is of clinical significance to avoid recurrent ischemic progress, prevent myocardial infarction, and thereby improve long term prognosis.

Invasive coronary angiography (ICA) is currently the gold standard procedure for assessment of ISR.

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However, ICA is both costly and invasive, and is associated with potentially serious complications [5, 6]. CT coronary angiography (CTCA) has been proved to be a reliable non-invasive alternative to ICA for detection of coronary artery stenosis since the advent of 64-slice CT [7]. Nevertheless, the value of CTCA for evaluation of stent patency remains uncertain and needs to be validated in the recent guideline on CTCA [8]. We aim to evaluate the value of CTCA for detection of ISR, and further identify the proper population for CTCA follow-up based on stent models (materials and strut thickness) and calibers.

Methods

Patient population

Between January 2008 and July 2010, consecutive clinically-ordered patients with prior coronary stent implantation in native vessels were prospectively enrolled in our study. 4 different DES with varied diameters (2.25–4.5 mm) were included: Taxus Liberté (Boston Scientific, US), Cypher Select (Cordis, US), Endeavor (Medtronic, US) and Firebird2 (MicroPort, China). Follow-up CTCA and repeat ICA were performed in all cases within an interval of 2 weeks. Exclusion criteria for CTCA include renal insufficiency (serum creatinine > 1.5 mg/dl), allergy to contrast media, clinical history of uncontrolled hyperthyroidism or multiple myeloma, atrial fibrillation or other rhythm irregularity, and inability to perform breath hold. All patients gave written informed consent, and the study protocol was approved by the hospital ethics committee.

Scan protocol of CTCA

A 64-slice multidetector CT (Lightspeed VCT 64, GE, Milwaukee, US) was employed for scanning. β -blocker (25–50 mg) was administered orally in patients with heart rate >65 bpm. A bolus of contrast media (Iopamidol, 370 mg iodine/ml, Schering AG, Berlin, German) was injected into antecubital vein at the rate of 4.5–5 ml/s, followed by a 20–40 ml saline flush by using dual-barrel power injector (Tyco, Cincinnati, US). The amount of the contrast media was determined according to the patient's body weight and scan time. A test bolus was firstly injected and the

region of interest was placed within ascending aorta to determine a proper delay time, which was defined as 4 s plus the peak time of ascending aorta. Retrospective ECG-gated CTA was performed with collimation = 64×0.625 mm, slice thickness = 0.625 mm, rotation time = 350 ms, pitch and current were ECG modified (ECG-dependent dose modulation technique was applied, full dose during the R-R interval of 40–80%), and tube voltage = 120 Kvp.

Image reconstruction and analysis

For better delineation of both vessel wall and stent lumen [9], two sets of axial images were reconstructed with different kernels: smooth kernel (soft, GE) and sharp kernel (bone, GE) with slice thickness of 0.625 mm. Data was transferred to an offline workstation (ADW4.3, GE) for further analysis. Axial images, curved planar reformation (CPR), multiplanar reformation (MPR) as well as volume rendering (VR) images were available for evaluation. All images were evaluated independently by two radiologists experienced in CTCA who were blinded to the number, location, diameter, and type of stents, to the clinical history of patients. Disagreements between the two readers for any image set were resolved by consensus, and the consensus findings were used in all assessments of diagnostic performance.

A standard American Heart Association (AHA) segmentation was employed for evaluation of all segments [10]. Image quality of stent was assessed by using a 3-point semi-quantitative scale: 3 = excellent (absence of strut artifact), 2 = acceptable (presence of less strut artifact, but still diagnostic), 1 = poor (presence of severe strut artifact, non-diagnostic) (Fig. 1). The presence and extent of ISR were visually and semi-quantitatively classified into 3 grades (Fig. 2): grade 1 none or slight neointimal proliferation with absence of ISR, grade 2 mild neointimal proliferation with ISR < 50%, grade 3 neointimal proliferation with ISR \geq 50% or occlusion. Grade 3 was considered as binary ISR on CTCA.

ICA procedure and analysis

The ICA was performed with standard techniques, and at least 2 different views were obtained for each main vessel. All segments were evaluated by 2 skilled observers who were blinded to the results of CTCA.

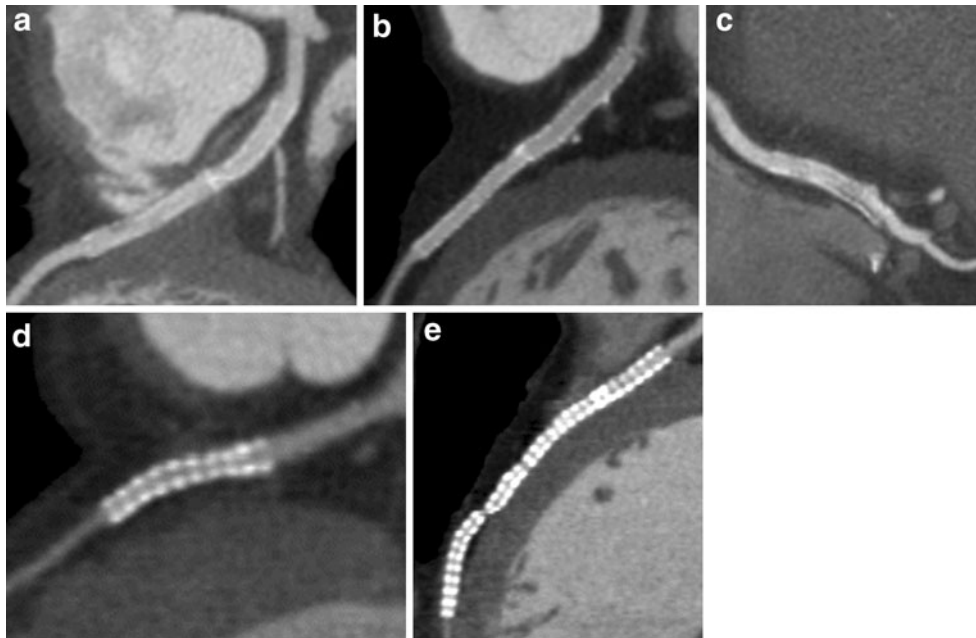


Fig. 1 Comparison of image quality of different stents by using 3-point semi-quantitative scale. **a** Firebird2, (3.0 × 18 mm, 3.0 × 23 mm), score 3. **b** Endeavor, (3.0 × 24 mm, 3.0 × 24 mm), score 3. **c** Taxus Liberté, (3.0 × 28 mm), score

3. **d** Cypher Select, (3.0 × 23 mm), score 2. **e** Cypher Select, (3.0 × 18 mm, 3.0 × 23 mm, 2.75 × 13 mm, 2.75 × 18 mm), score 1

Disagreements between the two readers were resolved by consensus. The percent diameter stenosis (%DS) was calculated by quantitative coronary angiography, employing the same grading system as of CTCA. Binary ISR or significant stenosis (>50%) in non-stented segment was considered for further interventions.

Statistical analysis

Sensitivity, specificity, positive (PPV) and negative predictive values (NPV) of diagnostic accuracy of CTCA were calculated on patient-based, segment-based and stent-based analysis respectively, using ICA as the gold standard. A further comparison of diagnostic accuracy of ISR on CTCA between stents of different models and calibers was carried out. Unassessable stents and non-stented segments were regarded as having binary ISR and significant coronary artery stenosis (>50%) for further analysis, as ISR and significant stenosis could not be excluded in those segments. Comparisons of quantitative variables were performed by one-way analysis of variance for normally distributed variables. SPSS 13.0 (IBM, US) was used for data analysis. A probability value of 0.05 was considered to be statistically significant.

Results

Patient characteristics and stent parameters

83 patients (mean age: 66.66 ± 9.42 , range 46–83 years, 62 males and 21 females) with 171 stents (stent per patient: 2.1 ± 1.22 , range 1–6 stents) were finally included in our study. The average interval between CTCA and last stenting procedure was 16.92 ± 6.27 months (range 4–31 months). The dose length product (DLP) of CTCA was 550.36 ± 49.27 mGy cm (range 441–660 mGy cm). An ICA was performed in all patients with an interval of 6.93 ± 2.63 days (range 1–14 days) of the CTCA. Detailed stent parameters were given in Table 1 and Table 2.

Comparison of image quality between different stent groups

According to the semi-quantitative score, the image quality of Firebird, Endeavor and Taxus were markedly better than Cypher in large caliber group (≥ 3 mm) ($P < 0.001$) (Table 2). Firebird, Endeavor and Taxus had no unassessable stents in those subsets

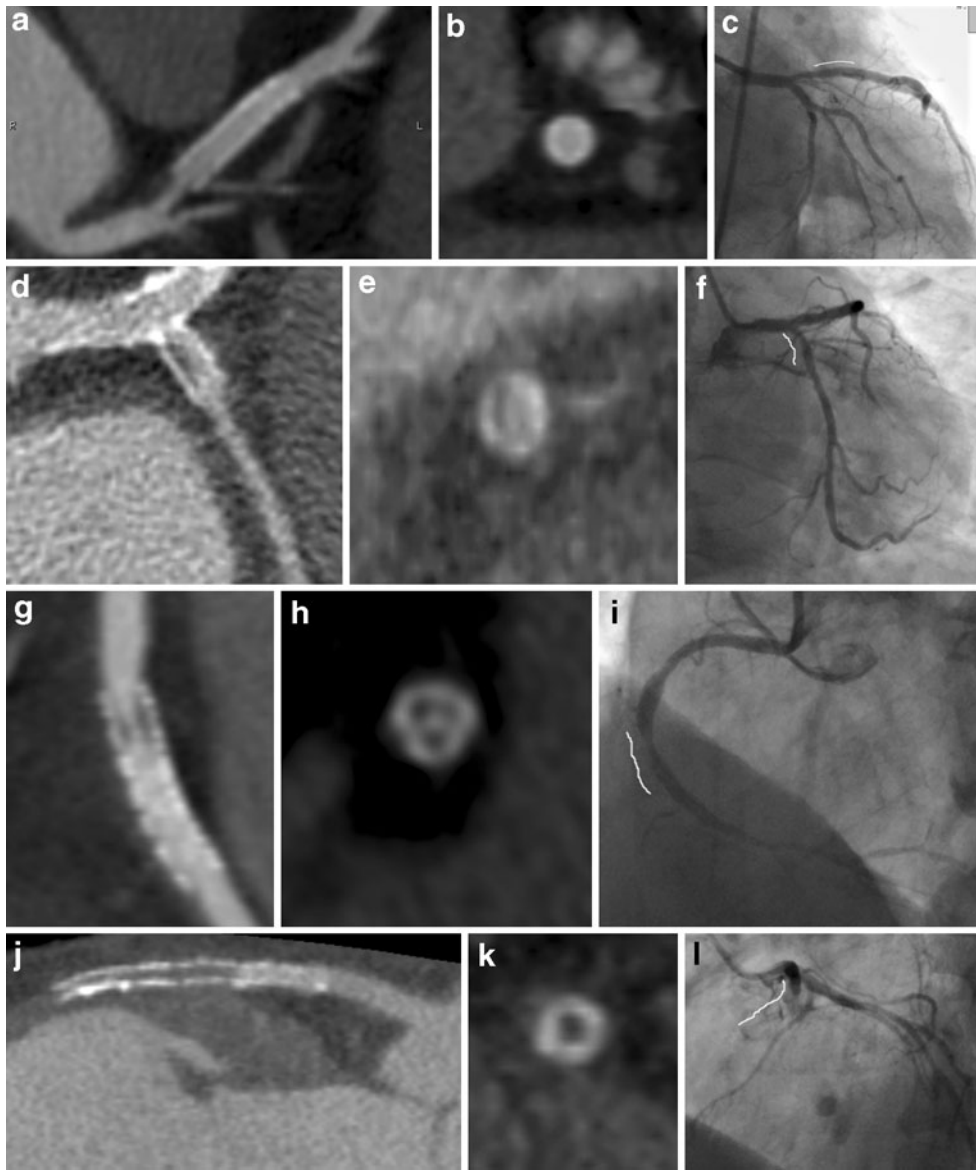


Fig. 2 ISR Grading: CTCA compared to ICA. The *white lines* on the figures show the sites of stents. **a** to **c** are Grade 1 (show absence of ISR). **a** The long-axis view of one Endeavor stent placed in proximal left anterior descending artery (LAD) (3.5×16 mm) on CTCA. **b** The short-axis view of stent on CTCA. **c** The Invasive coronary angiography (ICA) image. **d** to **f** are Grade 2 (show ISR < 50%). **d** The long-axis view of one Taxus stent placed in proximal left circumflex artery (LCx) (3.0×8 mm) on CTCA. **e** The short-axis view of stent on CTCA. **f** The Invasive coronary angiography (ICA) image. **G**

to **I** are Grade 3 (show ISR > 50%). **g** The long-axis view of one Taxus stent placed in middle right coronary artery (RCA) (3.0×20 mm) on CTCA. **h** The short-axis view of stent on CTCA. **i** The Invasive coronary angiography (ICA) image. **J** to **l** are Grade 3 (show total occlusion). **j** The long-axis view of two Firebird stents placed in proximal LAD (3.0×18 mm) and proximal-middle LAD (2.75×18 mm) on CTCA. **k** The short-axis view of stent on CTCA. **l** The Invasive coronary angiography (ICA) image

while Cypher had 33.3% (7/21) unassessable stents. For small caliber group, the image quality dropped significantly and the unassessable stents of Firebird,

Endeavor, Taxus and Cypher were 31.8% (7/22), 69.2% (9/13), 50% (14/28) and 92.3% (12/13), respectively. Firebird has the lowest unassessable

Table 1 Stents parameters

Stents per patient	2.06 ± 1.19
Stented vessel	
LM	2 (1.2%)
LAD	79 (46.2%)
LCx	36 (21.1%)
RCA	54 (31.6%)
Stent material (n = 171)	
Stainless steel	90 (52.6%)
Cobalt alloy	81 (47.4%)
Stent morphology (n = 171)	
Thick strut (>100 μm) with closed-cell	34 (19.9%)
Thick strut (>100 μm) with open-cell	89 (52%)
Thin strut (≤100 μm) with open-cell	48 (28.1%)
Stent diameter (nominal) (n = 162)	
4.5 mm	2 (1.2%)
4.0 mm	4 (2.3%)
3.5 mm	31 (18.1%)
3.0 mm	58 (33.9%)
2.75 mm	36 (21.1%)
2.5 mm	27 (15.8%)
2.25 mm	13 (7.6%)

LM left main artery, LAD left anterior descending artery, LCx left Circumflex artery, RCA right coronary artery

rate and best semi-quantitative score in small caliber group. Hence, the thinnest stent (Firebird) has the best image quality while the thickest stent (Cypher) has the worst. As Taxus and Endeavor have similar strut thickness and cell-design, comparison of image quality between those two was carried out in both large and small caliber groups, to determine the influence of stainless steel and cobalt alloy on image quality of CTCA. The results showed there is no statistical significance between image quality of Taxus and Endeavor in both subgroups ($P > 0.05$).

Table 2 Stents properties and image quality

	Total strut thickness (μm)	Material	Cell design	Image quality score (nominal diameter ≥ 3 mm)	Image quality score (nominal diameter < 3 mm)
Cypher Select	154	Stainless steel	Closed-cell	1.76 ± 0.62	1.08 ± 0.28
Taxus liberte	127	Stainless steel	Open-cell	2.64 ± 0.49	1.54 ± 0.58
Endeavor	107	Cobalt alloy	Open-cell	2.85 ± 0.37	1.31 ± 0.48
Firebird2	86	Cobalt alloy	Open-cell	2.81 ± 0.4	1.86 ± 0.71

Binary ISR and non-stented segment stenosis: compare CTCA with ICA

16 binary ISR (≥50% or occlusion, grade 3) were identified on ICA within 16 stents (9.36%) in 13 patients. Among those ICA-proved binary ISR, 12 stents were correctly diagnosed by CTCA while another 4 stents were unassessable on CTCA. The diagnostic performance of each stent group was described in detail in Table 3.

Firebird, Endeavor and Taxus showed excellent diagnostic accuracy in their large caliber group (≥3 mm) and all binary ISR were correctly detected by CTCA in those subsets. All stents in this population were found to be assessable. Nevertheless, Low PPV and specificity were observed in small caliber group of Firebird, Endeavor and Taxus, mainly due to increased number of unassessable stents. Cypher, however, was revealed to be inferior to other 3 counterparts in both large and small caliber groups.

Other than Grade 3 ISR, ICA revealed 14 stents of Grade 2 ISR and 141 stents of Grade 1 (Table 4). The diagnostic accuracy of CTCA grading were 68.8% (97/141), 50% (7/14) and 75% (12/16) for Grade 1, 2 and 3 groups. When excluding unassessable stents, the values were dramatically raising to 98% (97/99), 70% (7/10) and 100% (12/12) respectively.

In addition to stent based analysis, a further patient based and segment based analysis were carried out (Table 5). Binary ISR or significant coronary stenosis (>50%) in non-stented segments could be reliably excluded with high NPV and sensitivity per patient as well as per segment.

Discussion

Since ISR is a major complication of coronary intervention procedures, an early diagnosis is of

Table 3 Validation of CTCA compared with ICA for binary ISR of 4 different stent models

	PPV	NPV	Sensitivity	Specificity
Cypher Select (n = 34)	10.5% (2/19)	100% (15/15)	100% (2/2)	46.9% (15/32)
Nominal diameter \geq 3 mm (n = 21)	14.3% (1/7)	100% (14/14)	100% (1/1)	70% (14/20)
Nominal diameter < 3 mm (n = 13)	8.3% (1/12)	100% (1/1)	100% (1/1)	8.3% (1/12)
Taxus Liberte (n = 56)	25% (5/20)	100% (36/36)	100% (5/5)	70.6% (36/51)
Nominal diameter \geq 3 mm (n = 28)	75% (3/4)	100% (24/24)	100% (3/3)	96% (24/25)
Nominal diameter < 3 mm (n = 28)	12.5% (2/16)	100% (12/12)	100% (2/2)	46.2% (12/26)
Endeavor (n = 33)	25% (3/12)	100% (21/21)	100% (3/3)	70% (21/30)
Nominal diameter \geq 3 mm (n = 20)	66.7% (2/3)	100% (17/17)	100% (2/2)	94.4% (17/18)
Nominal diameter < 3 mm (n = 13)	11.1% (1/9)	100% (4/4)	100% (1/1)	33.3% (4/12)
Firebird2 (n = 48)	46.2% (6/13)	100% (35/35)	100% (6/6)	83.3% (35/42)
Nominal diameter \geq 3 mm (n = 26)	80% (4/5)	100% (21/21)	100% (4/4)	95.5% (21/22)
Nominal diameter < 3 mm (n = 22)	25% (2/8)	100% (14/14)	100% (2/2)	70% (14/20)

CTCA computed tomography coronary angiography, ICA invasive coronary angiography, ISR in-stent restenosis, PPV positive predictive value, NPV negative predictive value

Table 4 Comparison of ISR Grading between ICA and CTCA

CTCA Grading	ICA Grading		
	Grade 1	Grade 2	Grade 3
Grade 1	97	1	0
Grade 2	2	7	0
Grade 3	0	3	12
Unassessable by CTCA	42	3	4

CTCA computed tomography coronary angiography, ICA invasive coronary angiography, ISR in-stent restenosis

clinical significance to prevent secondary myocardial infarction, and therefore improve long term prognosis. ICA is currently the most applied and reliable modality for ISR diagnosis. However, the incidence of ISR has been decreased significantly since the use of drug-eluting stents [11, 12] and negative ICA findings in symptomatic post-stenting patients are not

unusual. Thus, an alternative non-invasive imaging modality to ICA may markedly reduce the number of negative ICA as well as undesired complications.

64-slice CT has no doubt played an irreplaceable role in non-invasive diagnosis of coronary artery disease with high sensitivity and specificity when comparing to ICA [7]. Previous studies have also shown that CTCA has a high sensitivity and specificity for diagnosis of ISR, which ranged from 75 to 95% and 74–98% respectively [9, 13–17]. However, all those studies did not include enough number of stents with diameter less than 3 mm and did not compare the performance between stents of different materials and strut thickness. Thus, those results might overestimate the diagnostic performance of CTCA. In our experience, the number of unassessable stents increases remarkably as nominal diameter decreases, and there is for sure varied extent of strut

Table 5 Diagnostic accuracy of CTCA in detecting both binary ISR and significant coronary artery stenosis in non-stented segments, per patient, per segment and per stent

	PPV	NPV	Sensitivity	Specificity
Patient based analysis (n = 83)	71.9% (41/57)	100% (26/26)	100% (41/41)	61.9% (26/42)
Segment based analysis (n = 1,228)	53.9% (48/89)	100% (1,139/1,139)	100% (48/48)	96.5% (1,139/1,180)
Stent based analysis				
With unassessable stents (n = 171)	25% (16/64)	100% (107/107)	100% (16/16)	69% (107/155)
Without unassessable stents (n = 122)	80% (12/15)	100% (107/107)	100% (12/12)	97.3% (107/110)

CTCA computed tomography coronary angiography, ICA invasive coronary angiography, ISR in-stent restenosis, PPV positive predictive value, NPV negative predictive value

artifact between stents of same caliber but different strut thickness. For this reason, our study mostly focused on the impact of those factors on the diagnostic performance of CTCA.

Stent-related factors affecting CTCA imaging

The results of our study showed that stent diameter is the most important factor affecting image quality. Stents with nominal diameter ≥ 3 mm have best image quality score, lumen visibility and excellent diagnostic performance comparing to ICA, except for Cypher stent. On the other hand, stents with nominal diameter less than 3 mm were revealed to have low PPV and specificity for diagnosis of ISR, mainly due to much more severe strut artifact, resulting in large number of unassessable stents.

Firebird, Taxus and Endeavor are both having open-cell design and with metal strut thickness less than 100 μm , which is thought to be another main factor affecting strut artifact. Those 3 stents showed similar diagnostic performance between large caliber groups, despite different stent materials. For small caliber group, Firebird showed best image quality and diagnostic accuracy, mainly thanks to its thinnest metal strut thickness. Considering the large sample number of each subgroup, the results of our study are believed to be reliable and we are convinced that there is no significant difference between stents of stainless steel and cobalt alloy in terms of strut artifact as well as diagnostic performance for ISR.

Cypher, however, showed reduced diagnostic performance even in large caliber group. Better performance is only acquired when diameter is ≥ 3.5 mm. The underlying reason is thought to be thicker metal strut with closed-cell system. Cypher has much thicker metal strut (140 μm) than its stainless steel counterpart Taxus (97 μm), and is the only stent with closed-cell design, all making it have the most severe strut artifact. Therefore, CTCA evaluation of Cypher stent with nominal diameter less than 3.5 mm seems to be unpractical and is not recommended for the use of post-stenting follow-up.

Proper population for CTCA follow-up

Based on the above findings of our study, stents with nominal diameter ≥ 3 mm (except for Cypher stent) have excellent diagnostic performance for ISR, and

may be useful for CTCA follow-up. On the other hand, Cypher stents and other stents with nominal diameter less than 3 mm yield impaired diagnostic performance and are not recommended for CTCA follow-up. Notably, although there is a large number of unassessable stents in small caliber group, the overall NPV and sensitivity of remain perfect (100%). That means a clinically-significant binary ISR can be confidently excluded by a negative CTCA examination.

Therefore, the best candidates for this examination are patients with atypical symptoms and stents' property meeting the above criteria. CTCA in those patients can reliably exclude binary ISR as well as significant stenosis in non-stented segments with high probability, and save patients from unnecessary ICA. Asymptomatic patients shall be followed up only clinically, and patients with typical symptoms should be referred directly for angiography.

Challenges in CTCA and tips for improvement

The image quality of CTCA is sensitive to various factors, which include stent-related artifacts and patient-related artifacts. The key for a successful study is to reduce those artifacts as much as we can.

For stent-related artifacts, as has been introduced by many other authors, a proper convolution kernel (bone, sharp) of reconstruction can effectively reduce beam hardening artifacts [13, 18], which is the major type of artifact that complicates the imaging of coronary stents. Hence, pair images of 2 reconstruction kernels (soft or smooth, bone or sharp) 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, thorough explanation of the examination and good training of breath-holding are the initial steps to ensure good image quality. In addition, heart rate shall be controlled with administration of beta-blocker.

Finally, combination of proper reformation images can help to estimate the lesion extent more precisely. As ISR secondary to a neointimal proliferation might be eccentric, an improper angle of CPR may under-or overestimate the extent of ISR. In our experience, a perpendicular view (short axis view of stent) is the most reliable view for the assessment of ISR extent

because both eccentric and concentric lesion can be clearly visualized in it.

Study limitations

The number of ISR in our study is relatively small and additional studies in larger populations are warranted before widespread clinical adoption of CTCA. Furthermore, there are far more other types of stent widely used in clinical application. Previous in vitro studies have revealed varied performance of 29–68 different types of stents [19, 20]. Further in vivo studies have to be carried out to cover the whole stent catalogue in order to establish a complete profile of each individual.

Conclusions

Stent diameter and strut thickness are 2 underlying stent-related factors affecting diagnostic performance of CTCA. Binary ISR can be correctly diagnosed and excluded in large caliber groups of Firebird, Taxus and Endeavor, with stent diameter ≥ 3 mm. Consequently, CTCA follow-up in symptomatic patients is promising, although additional research is warranted.

Conflict of interest None.

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