ORIGINAL ARTICLE

Scoring model to predict low image quality of drug-eluting stent evaluated by computed tomography coronary angiography

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Abstract

Evaluation of in-stent restenosis (ISR) by computed tomography coronary angiography (CTCA) is less invasive but often impossible. We aimed to create a scoring model for predicting which drug-eluting stents (DES) cannot be evaluated with CTCA. We enrolled 757 consecutive implanted DES assessed with CTCA. Non-diagnostic evaluation was defined as poor/ not evaluative by two different observers. These stents were randomly divided into a derivation ($n = 379$) and validation ($n = 378$) group. In the derivation group, we assessed predictors using logistic regression analysis and created a scoring model that would stratify non-diagnostic evaluation of DES-ISR. The validity of this scoring model was evaluated in the validation group using receiver-operating characteristic analysis. The percentage of non-diagnostic stents was 19/21% in the derivation/validation group ($p = 0.71$). Non-diagnostic evaluation was independently associated with implanted stent diameter (2.25–2.5. vs. 2.5–3 vs. > 3.0 mm), severe calcification, stent-in-stent lesion, and type of DES (stainless vs. CoCr vs. PtCr) in the derivation group. The predicting system of implanted DES non-diagnostic by CTCA (PIDENT) for non-diagnostic evaluation, including these four baseline factors, was derived (C-statistic = 0.86 in derivation group, cutoff: 8 points). The PIDENT score had a high predictive value for non-diagnostic DES in the validation model (C-statistic = 0.87, sensitivity 86%, specificity 74%, cutoff 8 points, $p < 0.001$). The PIDENT score, consisting of baseline characteristics including implanted stent diameter, severe calcification, stent-in-stent lesion, and type of DES, could identify non-diagnostic evaluation of DES-ISR with CTCA. The PIDENT score was valuable in reducing nonevaluable and meaningless CTCA for DES-ISR.

Keywords Computed tomography angiography · Drug-eluting stent · In-stent restenosis

Introduction

Percutaneous coronary intervention is the most common revascularization procedure performed worldwide in patients with coronary artery disease [1]. Drug-eluting stents (DES)

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have remarkably reduced target lesion revascularization by preventing excessive neointimal hyperplasia inside stents [2, 3]. DES are now widely used for small vessel, long chronic total occlusion lesions, and multivessel lesions [4–7]. However, even with the use of DES, lesion complexity or patient comorbidities are associated with in-stent restenosis (ISR) [8].

Invasive coronary angiography (ICA) is still considered the gold standard for detecting ISR, but it is an invasive procedure with a significant risk of complications and high cost. Recently, computed tomography coronary angiography (CTCA) has become a standard diagnostic modality without ICA-related complications in the noninvasive assessment of coronary stents [9, 10]. The stress test is also a noninvasive method, but its diagnostic performance is not very high. Previous studies indicated that CTCA has high sensitivity and specificity for detecting ISR [11–13].

However, thick-strut thickness and stent diameter are reported to have poor diagnostic performance for ISR [11, 14, 15]. Assessment of DES-ISR using CTCA is not necessarily applicable for all patients because imaging quality is not always guaranteed.

Newer smaller diameter DES with a flexible design and thinner struts DES are available [16–18]. Stent diameter has been reported to be not associated with image quality and assessment ability by CTCA in the evaluation of thin-strut (< 140 μm) DES [19]. However, the predictive ability of CTCA for ISR of these stents has not been fully elucidated. CTCA is a less invasive diagnostic tool than conventional angiography but sometimes induces contrast-induced nephropathy or life-threatening allergy. We established a scoring model to predict which implanted DES cannot be evaluated by CTCA and validated the diagnostic performance of this model to reduce unnecessary CTCA for patient safety and cost-effectiveness.

Materials and methods

This study retrospectively included 756 DES implanted between January 2015 and August 2018 who underwent CTCA for clinical indications with an interval of > 1 month since the most recent stenting. The average time from PCI until CTCA was 45 ± 26 months. Exclusion criteria for CTCA were as follows: chronic kidney disease (serum creatinine > 1.5 mg/dL or glomerular filtration rate < 50 mL/min/1.73 m^2), allergy to contrast media, inability to hold breath, or other patient status contraindicating CTCA. Based on stents, they were randomly divided into a derivation

group (379 stents, 296 patients) and a validation group (378 stents, 290 patients). The study design is shown in Fig. 1. All patients provided written informed consent, and the study protocol was approved by the hospital ethics committee.
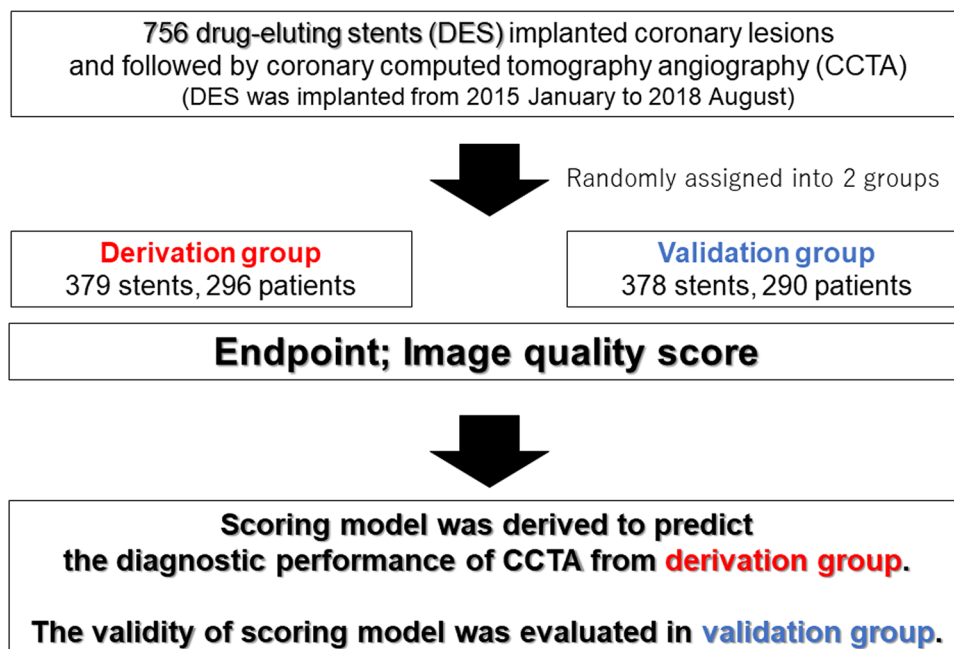
Imaging protocol

All patients were scanned with a 320-row slice scanner (INFX-8000 C/AquilionONE Vision Edition; Canon Medical Systems Corporation, Otawara, Japan). A β-blocker (oral metoprolol or intravenous propranolol 10–20 mg) was administered if the heart rate was ≥ 65 beats/min. A bolus of contrast medium was injected into the antecubital vein with an injection velocity of 3–5 mL/s. The total amount of contrast medium was estimated according to the patient's body weight and heart rate. A test bolus tracking method was used with the following parameters: collimation width 320×0.5 mm, rotation time 275 ms, tube voltage 120 kV, and effective tube current 600 mA. CTCA was performed during a single breath hold with an electrocardiogram (ECG)-synchronized method at an ECG dose modulation between 30 and 100% of the RR interval.

Multidetector CT image reconstruction and analysis

The CTCA data generated were transferred to an offline workstation (Ziostation 2; Ziosoft Inc., Tokyo, Japan) for image analysis. Cross-sectional multiplanar reconstruction images of the stents and curved-planar reconstruction images through the median of the stents were reconstructed to assess the in-stent lumen and transferred to Wizard.

Fig. 1 Study design

756 drug-eluting stents (DES) implanted coronary lesions
and followed by coronary computed tomography angiography (CCTA)
(DES was implanted from 2015 January to 2018 August)

Randomly assigned into 2 groups

Derivation group
379 stents, 296 patients

Validation group
378 stents, 290 patients

Endpoint; Image quality score

**Scoring model was derived to predict
the diagnostic performance of CCTA from derivation group.**

The validity of scoring model was evaluated in validation group.

Definition

CTCA image quality (IQ) was graded from 0 to 3 for each stent as follows: grade 0, poor/nonevaluable/non-diagnostic image quality (severe artifacts impairing accurate evaluation, stent segment classified as nonevaluable); grade 1, adequate image quality (moderate artifacts, acceptable for routine clinical diagnosis); grade 2, good image quality (minor artifacts, good diagnostic quality); and grade 3, excellent image quality (no artifacts) [20]. Images with grade 0 were defined as non-diagnostic and those with grades 1–3 as diagnostic (Fig. 2). The IQ was evaluated by two skilled observers. If their evaluation differed from each other, they discussed and made a final decision.

Prior to the initiation of the percutaneous coronary intervention procedure, information regarding selected risk factors was obtained from hospital records made at discharge. The following data were collected to reflect baseline clinical characteristics: age, sex, hypertension (systolic blood pressure > 140 mmHg), dyslipidemia (low-density lipoprotein cholesterol > 140 mg/dL or high-density lipoprotein cholesterol < 40 mg/dL), diabetes mellitus [fasting blood glucose > 126 mg/dL, glycated hemoglobin (National Glycohemoglobin Standardization Program) > 7.0%, or casual blood glucose > 200 mg/dL], past or current smoking status, and renal function evaluated via estimated glomerular filtration rates.

Coronary calcification was defined as obvious density within the arterial wall and at lesion sites that was readily apparent as an X-ray-absorbing mass during ICA. Severe calcification was defined as density noted without cardiac motion before contrast injection and generally involving both sides of the arterial wall [21]. Tortuous lesion is defined as three fixed bends during both systole and diastole in at least one epicardial artery, with each bend showing a 45° change in vessel direction [22]. Stent-in-stent lesions meant that the DES evaluated with CTCA was implanted to treat ISR lesions. The type of prior stent presenting with ISR was not considered. Type of DES were as follows: stainless DES included Cypher (Cordis, Warren, New Jersey), TAXUS Liberté (Boston Scientific Corporation, Natick, MA, USA), and Nobori (Terumo, Tokyo, Japan); PtCr-DES included PROMUS element and Synergy (Boston Scientific); and CoCr-DES included PROMUS (Boston Scientific), Xience series (Abbott Vascular, Santa Clara, CA, USA), Resolute Integrity (Medtronic, Santa Rosa, California), and Ultimaster (Terumo, Tokyo, Japan). An overlapping stent was defined as multiple stents implanted to treat long lesions.

Stent fracture detected with CTCA was diagnosed according to the following criteria: (1) partial or circumferential separation of the stent; (2) absence of a metallic stent strut on cross-sectional image, and (3) confirmation of radiodensity of < 300 Hounsfield units at the site of separation [23].
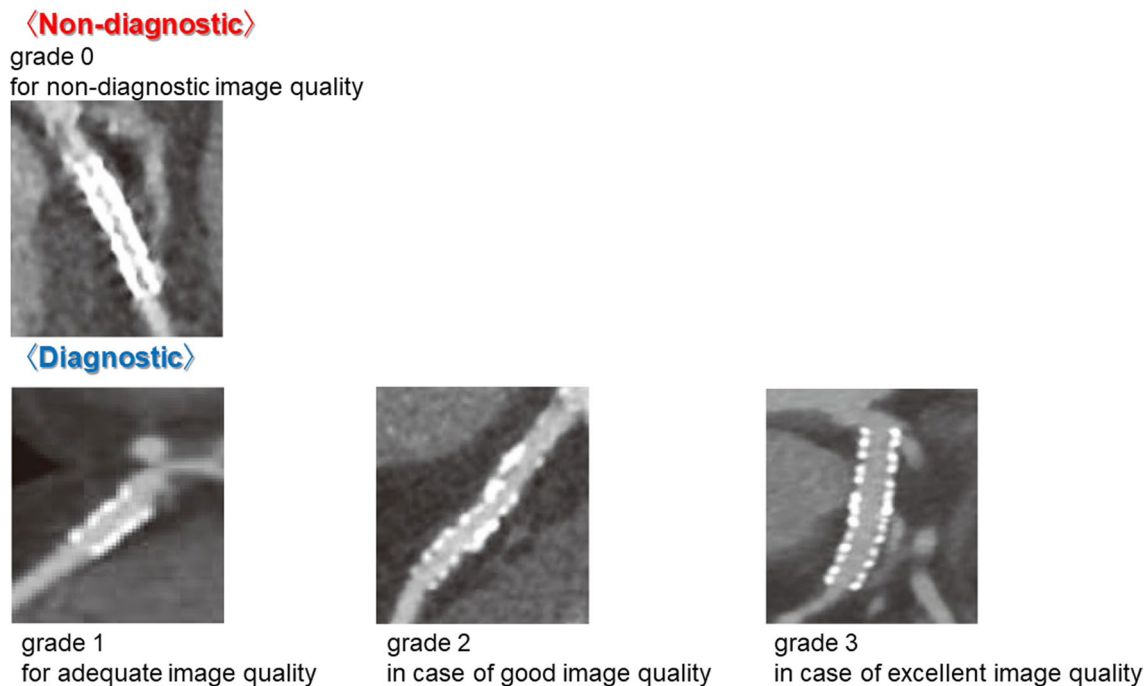

〈Non-diagnostic〉
grade 0
for non-diagnostic image quality

〈Diagnostic〉

grade 1
for adequate image quality

grade 2
in case of good image quality

grade 3
in case of excellent image quality

Fig. 2 Definition of image quality

Development of the scoring model

Risk scores were developed using a modified Framingham Heart Study approach [24]. The predictive value of the non-diagnostic DES with CTCA was determined using logistic regression models in the derivation group. Predictors with $p < 0.05$ after multivariate analysis were converted to points, and a total score was calculated for each patient by summation of those points. The validity of this scoring model was evaluated in the validation group. The performance of the scoring system for non-diagnostic DES with CTCA was evaluated by receiver-operating characteristic curve analysis, and the predictive ability of this score was determined using C-statistics.

Statistical analysis

Group randomization was performed as follows: (1) all stents were numbered with a random function, (2) they were arranged in a sequence of assigned numbers, and (3) the first half of the stents were classified as the derivation group, and the latter half were classified as the validation group.

Continuous variables are expressed as mean (SD), and categorical variables are expressed as numbers and percentages. A multiple logistic regression analysis was used to identify independent predictors of the non-diagnostic DES with CTCA. To identify independent predictive factors, we selected variables with $p < 0.10$ in the univariate logistic regression model and included them in the multivariate models simultaneously. Predictive values of target vessel location in the left anterior descending artery or left circumflex coronary artery compared with right coronary artery (RCA) as the referent, implanted stent diameter of 2.75–3.0 or 2.25–2.5 mm compared with > 3.0 mm as the referent, and type of DES in PtCr-DES or CoCr-DES compared with stainless DES as the referent were also assessed. All statistical analyses were performed using JMP® 15(SAS Institute Inc., Cary, NC, USA). p values of < 0.05 were considered statistically significant.

Results

Non-diagnostic DES by CTCA

Non-diagnostic DES was observed in 69 stents (19%) in the derivation group and 78 stents (21%) in the derivation group. The characteristics of non-diagnostic DES and diagnostic DES in the derivation group are shown in Table 1. Age, sex, body mass index, and prevalence of cardiac comorbidities were similar between the groups. The location of target lesions differed between the two groups ($p = 0.001$). All DES implanted in the left main trunk (LMT) were diagnostic, and

the percentage of DES implanted in the RCA was higher in the diagnostic DES group (34% vs. 16%). Severe calcification and stent-in-stent lesions were more frequently observed in the non-diagnostic DES group than in the diagnostic group (29% vs. 12%, $p < 0.001$). Distribution in the DES material differed between the two groups ($p = 0.002$). The percentage of PtCr DES was higher in the non-diagnostic DES group than in the diagnostic DES group (44% vs. 23%). The distribution of implanted stent diameter was different between the two groups, and the percentage of small stent use (2.25–2.5 mm) was significantly higher in the non-diagnostic DES group than in the diagnostic DES group (72% vs. 28%, $p < 0.001$). Stent diameter was also longer in the non-diagnostic DES group than in the diagnostic DES group [29 (SD 16) vs. 25 (SD 12) mm, $p = 0.01$]. Strut thickness was relatively greater in the non-diagnostic DES group than in the diagnostic DES group, but the difference was not statistically significant [95 (SD 23) vs. 100 (SD 24) μm, $p = 0.09$]. Stent fracture detected by CTCA was similarly observed between two groups (3% in non-diagnostic group vs. 2% in diagnostic group, $p = 0.75$).

Scoring model to predict non-diagnostic DES by CTCA

Multivariate analysis was performed including variables with a p value < 0.10 in comparison with non-diagnostic DES and diagnostic DES in the derivation group. DES implanted in LMT lesions were previously excluded from multivariate analysis because they all were diagnostic and unsuitable for analysis. As a result, implanted stent diameter [> 3.0 mm, odds ratio (OR) 1.00; 2.75–3.0 mm, (OR) 2.81, 95% confidence interval (CI) 1.81–7.25, $p = 0.03$; 2.25–2.5 mm, (OR) 4.96, 95% CI 2.41–12.5, $p < 0.001$], severe calcification (OR 5.12, 95% CI 2.33–12.3, $p < 0.001$), stent-in-stent lesion (OR 7.91, 95% CI 3.52–19.2, $p < 0.001$), type of DES [stainless, OR 1.00; PtCr, (OR) 3.11, 95% CI 1.30–6.45, $p = 0.006$; CoCr, OR 1.28, 95% CI 0.75–3.97, $p = 0.55$] were independent predictors of non-diagnostic DES by CTCA (Table 2). The predicting system of implanted DES non-diagnostic by CTCA (PIDENT) score was derived after the risk ratios were converted to risk score points (Table 3). The PIDENT score was similar between the two groups [6 (SD 3) vs. 6 (SD 3), $p = 0.88$]. The C-statistic for non-diagnostic DES by CTCA was 0.86 (95% CI 0.82–0.89, $p < 0.001$) in the derivation group. Sensitivity and specificity were 85% and 74%, respectively, with a cutoff value of 8 points (Fig. 3A). The distribution of PIDENT score and the percentage of non-diagnostic DES by CTCA is shown in Fig. 3B.

Table 1 Comparison of characteristics non-diagnostic DES and diagnostic DES in derivation group

Variables	Total (n=379)	Non-diagnostic (n=69)	Diagnostic (n=310)	p value (non-diagnostic vs diagnostic)
Age	68 ± 10	69 ± 9	68 ± 10	0.19
Male (n, %)	280	48 (70)	232 (75)	0.37
BMI (kg/m^2)	25 ± 4	24 ± 4	25 ± 3	0.8
Hypertension (n, %)	272 (72)	52 (75)	220 (71)	0.57
Diabetes mellitus (n, %)	109 (29)	21 (30)	88 (28)	0.64
Dyslipidemia (n, %)	218 (58)	40 (58)	178 (54)	0.58
CKD on HD (n, %)	11 (3)	4 (6)	7 (2)	0.29
AF (n, %)	12 (3)	3 (4)	9 (3)	0.55
Target vessel (n, %)				
LMT/LAD/LCX/RCA	14/119/102/114 (4/39/27/30)	0/36/22/11 (0/52/32/16)	14/113/80/103 (5/36/26/34)	<0.01
Severe calcification (n, %)	57 (15)	20 (29)	37 (12)	<0.01
Tortuous lesion (n, %)	37 (10)	7 (10)	30 (10)	0.78
Stent-in-stent lesion (n, %)	39 (10)	19 (28)	20 (6)	<0.01
Material of DES (n, %)				
Stainless/CoCr/PtCr	148/127/104 (39/34/27)	19/19/31 (28/28/44)	129/108/73 (42/35/23)	<0.01
Overlap stenting (n, %)	84 (22)	21 (30)	63 (20)	0.08
Stent diameter (n, %)				
2.25–2.5 mm/2.5–3/3 mm <	137/140/102 (36/37/27)	50/15/4 (72/22/6)	87/125/98 (28/40/32)	<0.01
Stent length (mm)	26 ± 13	29 ± 16	25 ± 12	0.01
Strut thickness (μm)	99 ± 24	95 ± 23	100 ± 24	0.09
Strut thickness ≥ 140 μm (n, %)	46 (12)	8 (12)	38 (12)	0.88
Stent fracture detected by CTCA (n, %)	9 (2)	2 (3)	7 (2)	0.75

BMI body mass index, *CKD* chronic kidney disease, *HD* hemodialysis, *AF* atrial fibrillation, *LMT* left main trunk, *LAD* left anterior descending, *LCX* left circumflex, *RCA* right coronary artery, *DES* drug-eluting stent, *CTCA* computed tomography coronary angiography

Table 2 Multivariate analysis for predictors of non-diagnostic DES

Variable	Odds ratio	95% CI	p value
Target vessel			
RCA	1		
LAD	1.16	0.82–3.11	0.52
LCX	1.31	0.79–3.31	0.48
Implanter stent diameter			
3.0 mm <	1		
2.75–3.0 mm	2.81	1.81–7.25	0.03
2.25–2.5 mm	4.96	2.41–12.5	<0.01
Severe calcification	5.12	2.33–12.3	<0.01
Stent-in-stent lesion	7.91	3.52–19.2	<0.01
Type of DES			
Stainless-DES	1		
PtCr-DES	3.11	1.30–6.45	<0.01
CoCr-DES	1.28	0.75–3.97	0.55
Overlap stenting	1.02	0.49–2.11	0.91
Stent length (per 5 increase)	1.32	0.92–1.62	0.53
Strut thickness (per 10 increase)	1.06	0.86–1.31	0.68

DES drug-eluting stent, *PtCr* platinum chrome, *CoCr* cobalt chrome

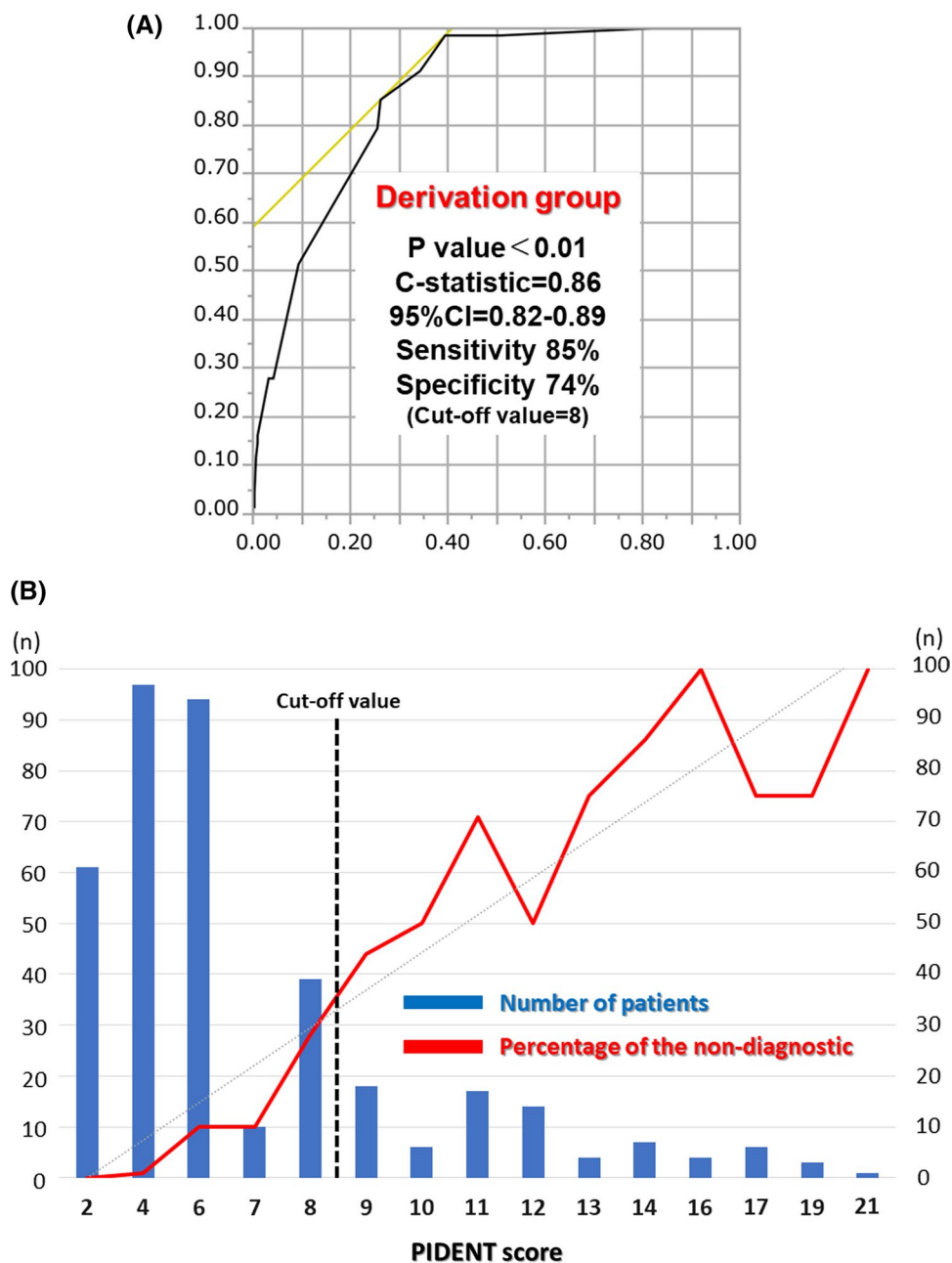**Table 3** PIDENT (predicting system of implanted DES non-diagnostic by CTCA) score

Variable	Score
Implanted stent diameter	
3.0 mm <	1
2.75–3.0 mm	3
2.25–2.5 mm	5
Severe calcification	5
Stent-in-stent lesion	8
Type of stents	
Stainless-DES	1
PtCr-DES	3
CoCr-DES	1

DES drug-eluting stent, *PtCr* platinum chrome, *CoCr* cobalt chrome

Performance of PIDENT score in the validation group

In the validation group, the c-statistic for non-diagnostic DES by CTCA was 0.87 (95% CI 0.83–0.90, $p < 0.001$). The

Fig. 3 A The performance of the scoring system for non-diagnostic DES with CTCA in derivation group. **B** The distribution of PIDENT score and the percentage of non-diagnostic DES by CTCA in derivation group

Discussion

The present study demonstrated that a new scoring system, PIDENT, was valuable for predicting non-diagnostic DES by CTCA and for avoiding meaningless CTCA with non-evaluable image quality. Calculation of this score is simple and derived from the following four factors: stent diameter,

sensitivity and specificity were 84% and 76%, respectively, with a cutoff value of 8 points (Fig. 4A). The distribution of PIDENT score and the percentage of non-diagnostic DES by CTCA is shown in Fig. 4B.
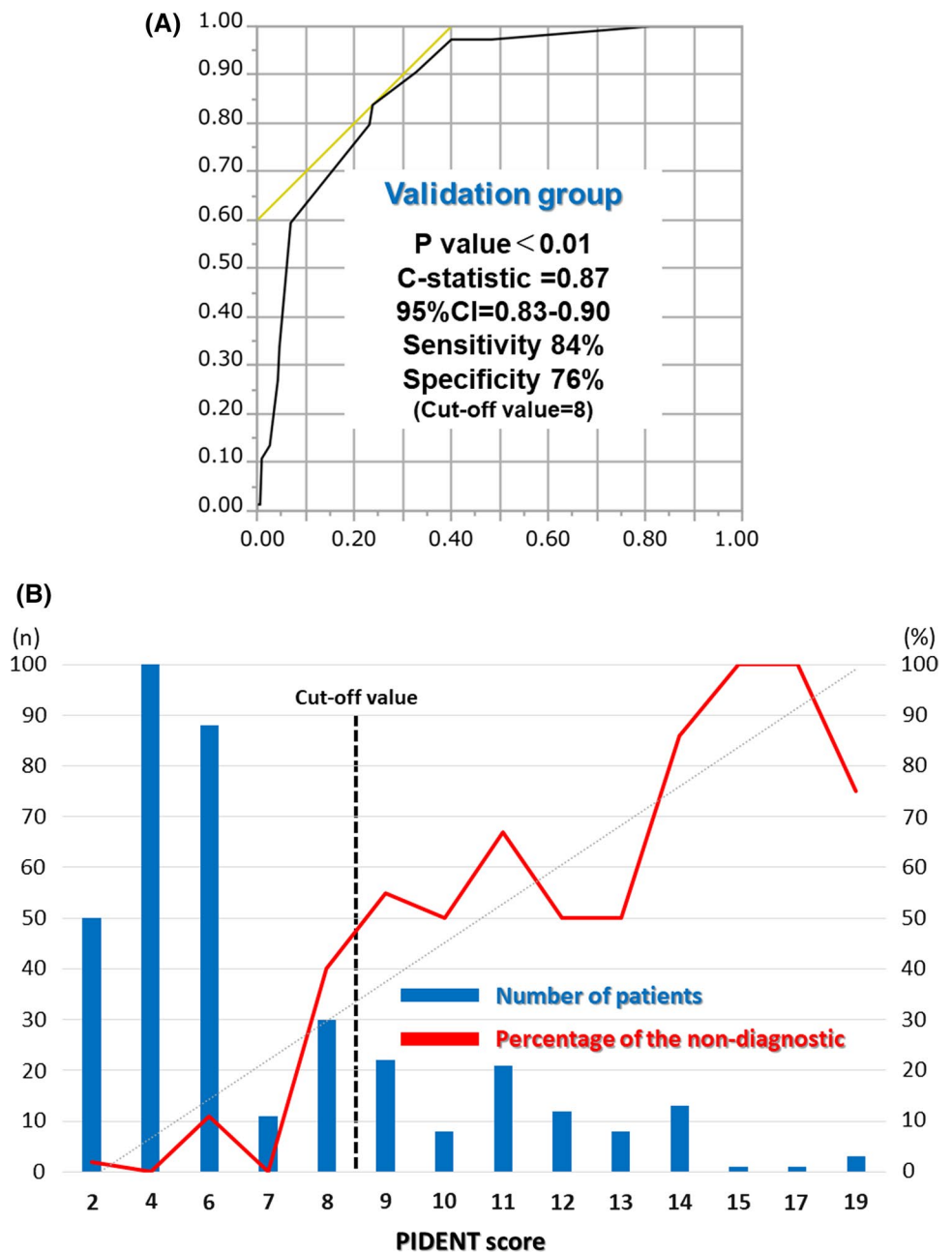
severity of angiographic calcification, presence or not of stent-in-stent lesion, and type of DES. The PIDENT score applied to the validation group in this study showed objectively high predictive performance.

A larger stent naturally provides fewer blooming artifacts and is more visible, which leads to more accurate assessment, whereas a stent diameter of 3 mm was likely to be a cutoff value of high or low assessment ability [15]. Although smaller stents (≤ 2.5 mm) are available, and the mid-term efficacy of these stents has also been reported [25, 26], the assessment ability of CTCA for these stents has not been clarified. In our study, small stents (≤ 2.5 mm) had a strongly negative predictive value for diagnostic performance. The

Fig. 4 A The performance of the scoring system for non-diagnostic DES with CTCA in validation group. **B** The distribution of PIDENT score and the percentage of non-diagnostic DES by CTCA in validation group

(A)

Validation group

P value < 0.01
C-statistic = 0.87
95%CI = 0.83-0.90
Sensitivity 84%
Specificity 76%
(Cut-off value=8)

(B)

(n)

Cut-off value

Number of patients

Percentage of the non-diagnostic

(%)

PIDENT score

PIDENT score conformed to the present day because this score differentiated stent diameter in detail compared with past studies.

A previous study reported that thick-strut stents (≥ 100 μm) had lower diagnostic accuracy than thin-strut stents, which suggested that thick-strut stents may reduce visualization of the lumen [27]. Strut thickness was not associated with the diagnostic performance of CTCA in this study. We consider the reason is that approximately 70% to 80% of DES in this study were second- or third- generation DES with strut thicknesses of < 100 μm. There is also the possibility that thin-strut DES overcame the problem of

artifacts caused by the strut, which reduce the visibility of CTCA. This point should be assessed in other studies with larger sample sizes in the near future.

The appearance of blooming artifacts caused by calcification is a problem peculiar to evaluation with CTCA; especially, bulky calcification strikingly reduces diagnostic performance. A subtraction CTCA method, wherein subtraction is performed using three-dimensional datasets acquired before and after the contrast medium reaches the target coronary artery, was reported to be feasible for patients with calcified coronary arteries [28, 29]. Subtraction CTCA has also been reported to provide significantly

higher diagnostic accuracy in the evaluation of ISR [30]. However, subtraction CTCA has several limitations, such as artifacts specific to the subtraction method and increased radiation dose. Routine clinical use of subtraction CTCA is difficult and not cost-effective, but appropriate use for selected patients could be feasible for evaluating patients when non-diagnostic CTCA is predicted. It should also be clarified that subtraction CTCA could evaluate implanted stents with severe calcification.

Stent-in-stent lesion is the strongest predictor of nondiagnosis with CTCA in this study. Stent-in-stent lesions were scored with 8 points and the cutoff value of the PIDENT score was also 8 points. This indicated that evaluation of stent-in-stent lesions should be performed not with CTCA but with other imaging modalities. Interestingly, overlapping stents were not predictors of nondiagnostic CTCA in this study. We considered the long overlapping length of two metals and neo-atherosclerosis causing ISR to reduce visibility of the lumen in stent-in-stent lesions.

Key improvements in design and metal alloy composition of the stent platform have been shown to affect acute stent performance and clinical outcome [31–33]. The combination of PtCr coronary stent platforms improved acute mechanical performance in terms of flexibility, deliverability, conformability, radial strength, and visibility under angiography [31]. PtCr-DES was associated with nondiagnostic CTCA in this study. The good angiographic visibility of the PtCr stent results from its increased radiopacity; however, in the evaluation with CTCA, increased radiopacity might cause blooming or motion artifacts and reduce the visibility inside the stents. Though, type of stents did not matter in the evaluation of large stent more than 3 mm diameter because "PtCr-DES" had only 3 points. PtCr-DES implanted for a small vessel or calcified lesion that reaches 8 points should not be evaluated with CTCA.

Late catch-up phenomena or neo-atherosclerosis of the in-stent lumen have been reported even in newer generation DES [34]. Importantly, the diagnostic performance of CTCA for DES-ISR is very high if implanted stents are clearly visualized [35, 36]. CTCA suggests that patients with stents assessed as visible without ISR can avoid ICA with its associated risks. ICA may not be suitable to assess or follow up ISR lesions on a regular basis, which is the same in the research field. When faced with patients who previously underwent DES implantation and were suspected to have angina pectoris, patients with a PIDENT score ≤ 8 could be evaluated with CTCA if there was no other contraindication for CTCA, but patients with a PIDENT score > 8 should be evaluated with other imaging modalities, including ICA. Thus, the PIDENT score was valuable in reducing nonevaluable and meaningless CTCA for DES-ISR.

Study limitations

The limitations of this study were as follows. First, only a limited number of patients in a single center were enrolled. Second, because this was a retrospective study, the selection of patients who underwent evaluation with CTCA could be biased by the physician's discretion. We did not perform CTCA for patients with uncontrolled AF tachycardia or with known severe calcified coronary artery. A lower rate of patients with AF, on hemodialysis and using a Rotablator could suggest such discretions indirectly. However, the CTCA in the patients in this study was performed for clinical indications so that the results of this study reflected real-world clinical practice. To evaluate the diagnostic performance of CTCA for DES, especially thin-strut DES, prospective studies with all-comer patients should be planned in the near future.

Conclusion

The PIDENT score consists of the following four factors for identifying non-diagnostic evaluation of DES-ISR with CTCA: stent diameter, severity of angiographic calcification, presence or not of stent-in-stent lesion, and type of DES. The PIDENT score was helpful for the effective use of CTCA in the evaluation of DES-ISR.

Declarations

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