A novel optical coherence tomography-based calcium scoring system can predict the stent expansion of moderate and severe calcified lesions

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Abstract. Coronary calcified lesions can exert serious effects on stent expansion. A calcium scoring system, based on optical coherence tomography (OCT), has been previously developed to identify relatively mild calcified lesions that would benefit from plaque modification procedures. Therefore, the present study aimed to establish a novel OCT-based scoring system to predict the stent expansion of moderate and severe calcified lesions. A total of 33 patients who underwent percutaneous coronary intervention (PCI; 34 calcified lesions were observed using coronary angiography) were retrospectively included in the present study. Coronary angiography and OCT images were subsequently reviewed and analyzed. Furthermore, a calcium scoring system was developed based on the results of multivariate analysis before the optimal threshold for the prediction of stent underexpansion in patients with moderate and severe calcified lesions was determined. The mean age of the patients was 67±10 years. The present analysis demonstrated that the final post-PCI median stent expansion was 70.74%, where stent underexpansion (defined as stent expansion <80%) was observed in 23 lesions. The mean maximum calcium arc, length and thickness, which were assessed using OCT, were found to be 230˚, 25.10 mm and 1.18 mm, respectively. A multivariate logistic regression model demonstrated that age and the maximum calcium arc were independent predictors of stent underexpansion. A novel calcium scoring system was thereafter established using the following formula: (0.16 x age) + (0.03 x maximum calcium arc) according to the β-coefficients in the multivariate analysis, with the optimal cut-off value for the prediction of stent underexpansion being 16.87. Receiver operating characteristic curve analysis demonstrated that this novel scoring system yielded a larger area under the curve value compared with that from a previous study's scoring system. Therefore, in conclusion, since the calcium scoring system of the present study based on age and the maximum calcium arc obtained from OCT was specifically developed in the subjects with moderate and severe calcified lesions, it may be more accurate in predicting the risk of stent underexpansion in these patients.

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Introduction

Coronary artery calcification is an integral process in atherogenesis, occurring in ≥90% of men and ≥67% of women >70 years of age (1). The pathogenesis of coronary calcification shares common pathways with bone formation, and eventually results in reduced vascular compliance, abnormal vasomotor responses and impaired myocardial perfusion. Calcified lesions are often harder to traverse and dilate, which pose higher risks of suboptimal stent deployment, angiographic complications and procedural failure (2). Coronary calcification presents a great challenge for percutaneous coronary intervention (PCI) and has an adverse impact on stent expansion and immediate treatment efficacy (3). The presence of calcified lesions strongly predicts the occurrence of stent thrombosis within a year of PCI and target lesion revascularization (4). Therefore, it is necessary to apply different approaches where calcified plaques are involved, prior to stent implantation, to achieve successful expansion.

Optical coherence tomography (OCT) utilizes near-infrared light directed at the vessel wall through a rotating single optical fiber coupled with an imaging lens within a short-monorail imaging sheath (5). By measuring the amplitude and time delay of the backscattered light, OCT generates high-resolution, cross-sectional and three-dimensional volumetric images of the coronary microstructure, which is an emerging intracoronary imaging modality that has been documented to accurately identify calcified lesions whilst also assessing the severity of calcification (6). A recent study reported that OCT-guided PCI for calcified lesions resulted in improved stent expansion (7). Furthermore, Fujino *et al* (8) showed that maximum calcium angle, maximum calcium thickness and calcium length were independent predictors of stent underexpansion, and demonstrated that calcium lesions with a maximum angle of >180˚ (defined as 2 points), a maximum thickness of >0.5 mm (1 point) and a length >5 mm (1 point) may be at risk of stent underexpansion in patients with relatively mild calcification. It was also revealed that the lesions with calcium score of 0 to 3 had excellent stent expansion, whereas the lesions with a score of 4 had stent underexpansion. However, whether this previously established OCT-based scoring system can be applied to patients with moderate and severe calcified lesions remains unclear. Therefore, the present study aimed to develop a novel scoring system for the prediction of stent underexpansion in patients with moderate and severe calcified lesions.

Materials and methods

Study population. A total of 78 patients aged 18-90 years old (68.1% male) were screened for the present study. These patients were diagnosed with moderate or severe calcified coronary lesions using coronary angiography or OCT and underwent OCT-guided stent implantation at Peking University People's Hospital (Beijing, China) between January 2016 and July 2021. The degree of calcification on coronary angiography was classified according to the Mintz criteria (9). The lesion was considered to be moderate or severe calcified lesion on OCT if it had multiple complex calcium imaging features, such as a maximum calcium length >5 mm, a thickness >0.5 mm or an arc >180˚. The exclusion criteria were as follows: i) Lack of pre-procedure or post-stent OCT images; ii) in-stent restenosis and chronic total coronary artery occlusion; iii) incomplete OCT images, in which critical parameters could not be analyzed or quantified; and iv) poor image quality.

Study design. The present retrospective study aimed to develop a novel OCT-based calcium scoring system to predict stent underexpansion in moderate and severe calcified lesions. Medical records, including coronary angiography and OCT images, of the eligible patients were reviewed. The patient demographic information, clinical manifestation, past medical history, family history of coronary heart disease, laboratory examinations and PCI procedural characteristics were recorded. The present study was approved by the Ethics Committee of Peking University People's Hospital (Beijing, China; approval no. 2018PHB154-01) and was performed according to the principles of The Declaration of Helsinki.

PCI procedure and OCT imaging data acquisition. Coronary angiography and stent implantation were performed according to the standard protocols. Angiographic images were recorded using 5-6F angiographic imaging catheter or guiding catheter at 15 frames/sec by radiographic systems (Innova IGS 530, GE Medical Systems; Azurion7 M12, Philips Healthcare). Angiographic image runs at all standard projection views for each vessel were saved. The contrast medium was injected manually at a constant speed of approximately 4 ml/sec until the distal vessel was filled. OCT imaging data were acquired using frequency-domain OCT (C7-XR™ or OPTIS™) and the Dragonfly™ Duo catheter (all purchased from Abbott Vascular; Abbott Pharmaceutical Co., Ltd.). After administration of intracoronary nitroglycerin, the Dragonfly™ Duo catheter was carefully advanced distal to the target lesion under fluoroscopic guidance. Then an automatic pullback OCT imaging was performed at a rate of 18 mm/sec (HD mode) or 36 mm/sec (S mode) throughout the entire lesion. During the session, contrast medium was flushed continuously with an injection rate of >5 ml/sec for the left coronary artery and >4 ml/sec for the right coronary artery depending on the vessel size. Based on the angiographic and OCT results, the decision of whether to perform rotational atherectomy (RA) or conventional angioplasty through cutting, scoring or using a non-compliant balloon prior to stent implantation was dependent on the discretion and skill of the surgeon. Briefly, in the presence of a multitude of complex calcium imaging features observable on the OCT image, an aggressive strategy of active RA was utilized followed by balloon angioplasty. Otherwise, the surgeon would first attempt a balloon angioplasty, followed by the RA procedure promptly in cases of inadequate balloon dilation. In cases of optimal balloon dilation or the apparent formation of a calcium crack (indicating adequate preparation of calcified lesions) after dilation on the OCT image, the stent would be implanted directly without the use of RA.

Quantitative coronary angiography (QCA) analysis. All angiography images were analyzed using the QAngio® XA software (version 7.3; Medis Medical Imaging Systems B.V.) by two independent interventional cardiologists (YM and QL), who were blinded to the clinical presentation and OCT results of the patients. The location, angulation and length of the calcified lesions, reference vessel diameter, minimum lumen diameter and diameter stenosis of the target lesions were assessed.

OCT imaging analysis. All OCT data were analyzed using Off-line Review Workstation software (version E.0.2; Abbott Vascular; Abbott Pharmaceutical Co., Ltd.) and based on procedures/guidelines described in dedicated expert consensus reports (10,11). This analysis was performed by two independent interventional cardiologists (YM and QL) who were blinded to the clinical and angiographic patient information.

In the present study, only lesions with a calcium arc ≥30˚ were included. Lesions were considered to be two separate calcified lesions if there was >1 mm of non-calcified plaque between the two. If the boundary of the calcified lesions was not obvious, then the maximum visible thickness would be quantified. Superficial calcification would be defined if the distance between the lesion and the lumen was <100 μm. Stent edge dissection was defined as the interruption of surface continuity at the stent edge (within 5 mm distal and proximal to the stent). Stent malapposition would be defined if the longitudinal distance from the stent surface to the lumen was greater than the stent thickness, whereas tissue protrusion would be defined if there was protrusion of the tissue into the lumen following stent implantation. The percentage of stenosis area and diameter were defined as the minimum lumen area/mean reference lumen area and the mean lumen

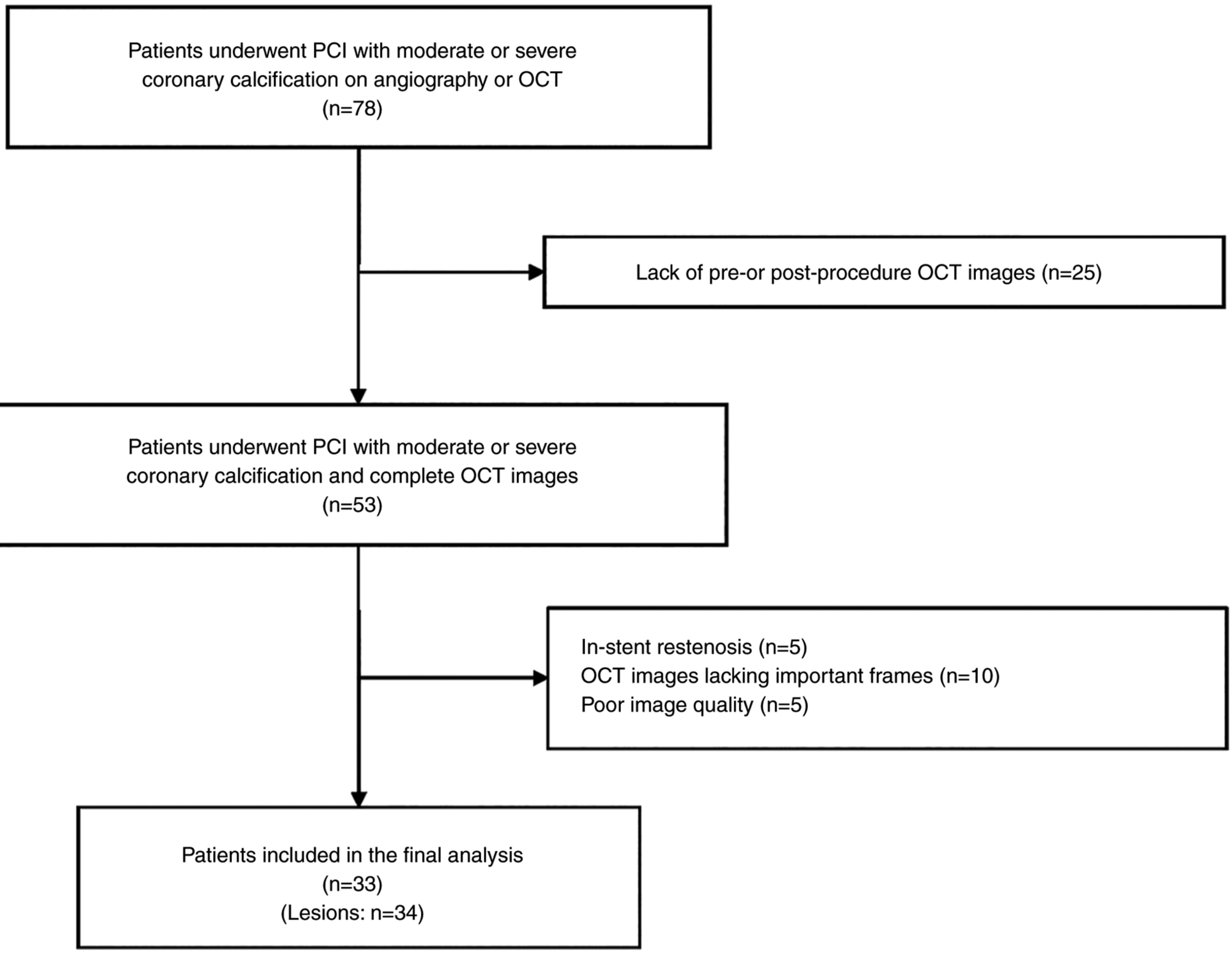

Figure 1. Study flowchart. A total of 78 patients diagnosed with moderate or severe calcified coronary lesions using coronary angiography or OCT, who underwent OCT-guided PCI were screened for the present study. Of the 45 patients excluded, 25 were excluded due to lack of pre- or post-procedure OCT images, five showed in-stent restenosis, 10 had inadequate OCT images in which important parameters could not be quantified and five were unable to analyze due to poor image quality. In total, 33 patients (34 lesions) were finally included. OCT, optical coherence tomography; PCI, percutaneous coronary intervention.

diameter at the narrowest site/mean reference lumen diameter, respectively. The stent expansion percentage was calculated as the minimum stent area/mean reference vessel area x100. According to the determined stent expansion, patients were divided into the adequate (stent expansion ≥80%) and poor (stent expansion <80%) stent expansion groups (11,12).

Statistical analysis. Statistical analysis was performed using the SPSS software (version 24.0; IBM Corp.). Categorical variables are presented as n (%) and were compared using either the χ^2 or Fisher's exact tests, as appropriate. The Shapiro-Wilk test was performed to examine the normality of distribution. Continuous variables with a normal distribution are presented as the mean ± standard deviation or are otherwise presented as the median and interquartile range. These variables were statistically compared using the unpaired Student's t-test or Mann-Whitney U test, as appropriate. Subsequently, the univariate logistic regression model was built and variables with P<0.10 were included in the multivariate logistic regression model with a step-wise algorithm. The maximum calcium length factor, which was deemed to be clinically relevant, also entered into the multivariate analysis. Significant variables were then included into the final calcium scoring system. Similar to the method of risk score establishment proposed in the Framingham Study, a novel calcium scoring system was developed by assigning weighted points for each variable (13). Receiver operating characteristic (ROC) curve analysis was performed to determine the optimal cut-off value for the novel scoring system for the prediction of stent underexpansion. The area under the curve (AUC) of the novel scoring system was compared with that proposed by Fujino *et al* (8) using the χ^2 test for two associated ROC curves. The inter-observer agreements for the OCT data were assessed by determining the intraclass correlation coefficients (ICC). P<0.05 (two-sided) was considered to indicate a statistically significant difference.

Results

Clinical and procedural characteristics. After excluding 25 patients due to paucity of pre-procedure or post-stent OCT images, a total of 53 patients with moderate or severe calcified lesions, identified using coronary angiography or OCT, who underwent stent implantation with the guidance of OCT and had complete OCT images, were included into the present study. Among these patients, 33 (34 lesions) were

Table I. Clinical characteristics of the patients.

Variables	Poor stent expansion (n=22)	Adequate stent expansion (n=11)	P-value
Age, years	70±10	59±8	0.003
Male, n (%)	12 (54.5)	8 (72.7)	0.456
Body mass index, kg/m^2	25.91±3.80	25.08±1.58	0.496
Hypertension, n (%)	16 (72.7)	7 (63.6)	0.696
Diabetes, n (%)[a]	10 (45.5)	4 (36.4)	0.719
Hyperlipidaemia, n (%)	16 (72.7)	9 (81.8)	0.687
Chronic kidney disease, n (%)[a]	2 (9.1)	1 (9.1)	>0.999
Smoking, n (%)	8 (36.4)	6 (54.5)	0.534
Family history of coronary heart disease, n (%)[a]	4 (18.2)	5 (45.5)	0.121
Prior percutaneous coronary intervention, n (%)[a]	8 (36.4)	4 (36.4)	>0.999
Clinical diagnosis, n (%)[a]			>0.999
Stable angina	5 (22.7)	2 (18.2)	
Unstable angina	13 (59.1)	7 (63.6)	
Acute myocardial infarction	4 (18.2)	2 (18.2)	
Left ventricular ejection fraction, %	69.03±5.71	66.32±6.04	0.298
Low density lipoprotein-cholesterol, mmol/l	2.06±0.77	2.06±0.53	0.992
Fasting plasma glucose, mmol/l	5.08 (4.52-5.58)	5.07 (4.72-6.10)	0.620
Estimated glomerular filtration rate, ml/min/1.73 m^2	82.16 (71.37-93.25)	93.95 (90.52-104.00)	0.036

[a]Compared using Fisher's exact test. Data are presented as the number (%), mean ± standard deviation or median (interquartile range).

finally included according to the aforementioned exclusion criteria (Fig. 1).

The mean age of the patients was 67±10 years and 20 of the patients were male. Furthermore, 23 (69.7%) patients had coexisting hypertension and 25 (75.8%) had hyperlipidemia. Of all 33 patients, 7 (21.2%) were diagnosed with stable angina pectoris, whereas 26 (78.8%) had acute coronary syndrome. Poor stent expansion occurred in 22 patients (23 lesions). The patients in the poor stent expansion group were significantly older compared with those in the adequate stent expansion group (70±10 vs. 59±8 years, respectively; P=0.003). In addition, the estimated glomerular filtration rate was significantly lower in the poor stent expansion group compared with that in the adequate stent expansion group (82.16 vs. 93.95; P=0.036; Table I). No significant difference was observed between the two groups with regards to the remaining clinical characteristics (Table I).

RA was performed in the modification of 19 (55.9%) lesions. Furthermore, 13 (38.2%) lesions were treated with scoring whereas 13 (38.2%) were treated with a non-compliant balloon prior to stent deployment. The median number of stents implanted was two and the median total length of stents was 44 mm. Compared with that in patients in the adequate stent expansion group [2 (18.2%)], the rate of RA performed during PCI was significantly higher in the patients in the poor stent expansion group [17 (73.9%); P=0.003; Table II]. There was no significant difference regarding the usage of balloons and stents between the two stent expansion groups (Table II).

Imaging analysis of the calcified plaques. The majority of patients had multi-vessel disease. The target lesions were mainly located in the left anterior descending artery. The prevalence of moderate and severe coronary calcification as assessed by angiography was up to 88.2% (30 lesions). All parameters of QCA analysis, including target vessel, degree of calcification, angulation of lesions, calcium length, minimum lumen diameter, minimum stent diameter and reference vessel diameter were comparable between the two stent expansion groups (Table III).

There were high levels of similarity between the two observers for the interpretation of the OCT images and the assessment of the maximum calcium arc (ICC=0.877), thickness (ICC=0.874) and length (ICC=0.968) (data not shown). The lesions all manifested as superficial calcifications, with a median maximum calcium arc of 230˚, median maximum calcium length of 25.10 mm and an average maximum calcium thickness of 1.18 mm. The overall final post-PCI median stent expansion was 70.74%. Furthermore, the maximum calcium arc (299 vs. 142˚; P=0.001; Table IV) and thickness (1.24 vs. 1.04 mm; P=0.029; Table IV) were significantly larger in the poor stent expansion group compared with those in the adequate expansion group, whereas the pre-stent diameter stenosis determined using OCT was significantly lower (52.76 vs. 66.29%; P=0.038; Table IV). The proportion of stent malapposition was significantly higher in the poor stent expansion group compared with that in the adequate stent expansion group (60.9 vs. 9.1%; P=0.011; Table IV), whereas the mean stent expansion

Table II. Procedural characteristics of the lesions.

Variables	Poor stent expansion (n=23)[a]	Adequate stent expansion (n=11)[a]	P-value
Scoring balloon, n (%)[b]	11 (47.8)	2 (18.2)	0.245
Maximum pressure, atm	14.00 (11.00-15.00)	12.00 (12.00-12.00)	0.545
Maximum diameter, mm	2.75 (2.50-2.88)	2.50 (2.38-2.62)	0.351
Non-compliant balloon, n (%)[b]	11 (47.8)	2 (18.2)	0.245
Maximum pressure, atm	18.00 (17.00-24.00)	13.50 (12.75-14.25)	0.091
Maximum diameter, mm	2.50 (2.50-2.50)	2.25 (2.12-2.38)	0.098
Semi-compliant balloon, n (%)	18 (78.3)	8 (72.7)	>0.999
Maximum pressure, atm	16.00 (14.00-16.00)	15.00 (13.50-16.50)	0.686
Maximum diameter, mm	2.50 (2.12-2.50)	2.50 (2.38-2.50)	0.885
RA, n (%)[b]	17 (73.9)	2 (18.2)	0.003
No. of RA procedures[b]	5 (3-7)	5 (4-5)	0.893
Maximum burr size, mm	1.50 (1.38-1.50)	1.50 (1.50-1.50)	0.725
Speed of burr, x10^4 r/min	15.00 (15.00-16.00)	16.60 (15.90-17.30)	0.212
Stent			
Number of stents[b]	2 (1-3)	1 (1-2)	0.126
Total stent length, mm	48.00 (37.50-69.00)	32.00 (28.00-57.00)	0.197
Maximum diameter, mm	3.00 (2.75-3.00)	2.75 (2.50-3.00)	0.165

[a]Represents the number of lesions. [b]Compared using Fisher's exact test. Data are presented as the number (%) or median (interquartile range). RA, rotational atherectomy.

was significantly lower in the poor stent expansion group (63.39±12.72 vs. 86.10±4.59%; P<0.001; Table IV).

Development of the novel calcium scoring system and comparisons with the previous scoring system. In the univariate analysis, age, maximum calcium arc and diameter stenosis were found to be significant predictors of stent underexpansion (P<0.05). Age [odds ratio (OR), 1.173; 95% CI, 1.036-1.438; P=0.042] and maximum calcium arc (OR, 1.023; 95% CI, 1.008-1.050; P=0.021) were demonstrated to be independent predictors of stent underexpansion in the multivariate logistic regression model (Table V). A novel calcium scoring system was established as follows: (0.16 x age) + (0.03 x maximum calcium arc), with the points of each variable assigned based on β-coefficients in the aforementioned multivariate analysis. In order to simplify the model and facilitate the calculation, each β-coefficient was rounded from 0.159 to 0.16, and from 0.023 to 0.03.

Subsequently, the optimal threshold for the prediction of stent underexpansion was identified using ROC curve analysis. The optimal cut-off value for the scoring system was determined to be 16.87 (sensitivity, 0.870; specificity, 0.909; AUC, 0.925; 95% CI, 0.836-1.014; P<0.001; Fig. 2). Representative OCT images are presented in Fig. 3. The pre-procedure OCT image of a 67-year-old patient showed severe coronary calcification with a maximum calcium arc of 290˚ at the narrowest site. The calculated calcium score of the lesion was 19.42 according to the novel calcium scoring system, which predicted the occurrence of stent underexpansion. The final post-stent OCT image indicated poor stent expansion as anticipated with a minimum stent area of 4.38 mm^2.

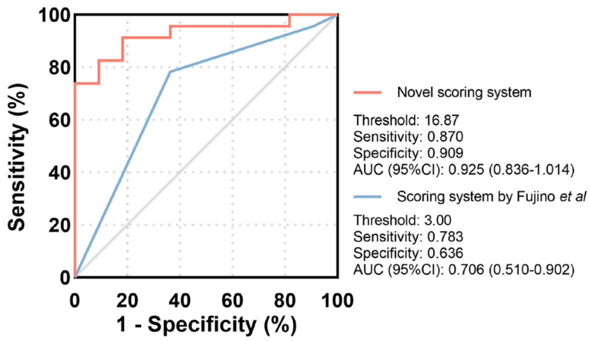

Figure 2. Receiver operating characteristic curve analysis of the novel calcium scoring system and the previously widely used system devised by Fujino *et al* (8). The optimal threshold of the novel calcium scoring system for predicting stent underexpansion was 16.87 with a sensitivity of 0.870, a specificity of 0.909 and an AUC of 0.925 (95% CI, 0.836-1.014; P<0.001). The AUC for the novel calcium scoring system was significantly larger (0.925 vs. 0.706; P=0.002). AUC, area under the curve.

A previous calcium scoring system developed by Fujino *et al* (8) was also applied, whereby the corresponding score for each patient was calculated before ROC curve analysis was performed to investigate the efficacy for the prediction of poor stent expansion. Compared with that of the Fujino *et al* (8) scoring system, the novel system in the present study, which incorporated age and the maximum calcium arc, was found to be superior for the prediction of stent underexpansion in the present study population, with a significantly larger AUC for the ROC analysis (0.925 vs. 0.706, respectively; P=0.002; Fig 2).

Table III. Quantitative coronary angiography analyses of calcified lesions.

A, Pre-procedure

Variables	Poor stent expansion (n=23)[a]	Adequate stent expansion (n=11)[a]	P-value
Multivessel disease, n (%)	19 (82.6)	11 (100.0)	0.280
Target vessel, n (%)[b]			>0.999
Left anterior descending	19 (82.6)	9 (81.8)	
Left circumflex	1 (4.3)	0 (0.0)	
Right coronary artery	3 (13.0)	2 (18.2)	
Degree of calcification, n (%)[b]			0.362
None or mild	2 (8.7)	2 (18.2)	
Moderate	14 (60.9)	8 (72.7)	
Severe	7 (30.4)	1 (9.1)	
Bifurcation, n (%)[b]	2 (8.7)	4 (36.4)	0.070
Angulation, n (%)[b]			0.203
≤90˚	22 (95.7)	10 (90.9)	
>90˚	1 (4.3)	1 (9.1)	
Calcium length, mm	35.77±20.66	26.03±12.34	0.227
RVD, mm	2.63 (2.38-2.83)	2.54 (2.32-2.64)	0.597
Minimum lumen diameter, mm	1.24±0.42	1.33±0.33	0.579
Diameter stenosis, %	53.43±13.27	48.02±12.92	0.290

B, Post-procedure

Variables	Poor stent expansion (n=23)[a]	Adequate stent expansion (n=11)[a]	P-value
RVD, mm	2.39 (2.12-2.53)	2.50 (2.26-2.94)	0.155
Minimum stent diameter, mm	2.19 (2.02-2.44)	2.33 (2.02-2.74)	0.382
Diameter stenosis, %	11.58 (6.45-15.02)	10.71 (6.80-15.51)	0.887

[a]Represents the number of lesions. [b]Compared using Fisher's exact test. Data are presented as the number (%), mean ± standard deviation or median (interquartile range). RVD, reference vessel diameter.

Discussion

The present study established a novel scoring system to effectively predict stent underexpansion in moderate and severe calcified lesions. The procedural characteristics and intracoronary imaging data of patients with moderate and severe coronary calcification who had undergone PCI were retrospectively analyzed. The main findings of the present study were as follows: i) The maximum calcium arc of lesions and patient age were independent predictors of stent underexpansion in patients with moderate and severe coronary calcification; and ii) the calcium scoring system based on these parameters may accurately predict the risk of stent underexpansion and guide the strategy of lesion modification, such as RA, in patients with moderate and severe coronary calcification.

It has previously been reported that the occurrence of stent underexpansion is increased in patients with severe calcified lesions, where incomplete stent expansion is known to be a common risk factor for stent thrombosis and in-stent restenosis (14-16). Severe coronary calcification is also an independent predictor of poor prognosis and increases the mortality rate (10.8 vs. 4.4%; P<0.001) or 1-year other adverse cardiac events defined as cardiac death, myocardial infarction, and target vessel revascularization after the treatment procedure (24.4 vs. 4.7%; P<0.001) (17,18). Therefore, a more aggressive strategy of lesion modification is needed prior to stent deployment to achieve efficient interventional treatment for this condition (19). Matsuhiro *et al* (20) previously reported that maximum calcium thickness <880 μm was a useful predictor of acceptable stent expansion (defined as 80% expansion) in moderate calcified lesions. Furthermore, Maejima *et al* (21) demonstrated that larger calcium arcs and a lower calcium thickness were associated with the formation of calcium cracks, which are important determinants of optimal stent expansion. However, in the present study it was demonstrated that the maximum calcium arc and the age of patients, but not the thickness of the lesions, actually had the more significant impact on stent expansion.

Table IV. Optical coherence tomography data of calcified lesions.

A, Pre-stent

Variables	Poor stent expansion (n=23)[a]	Adequate stent expansion (n=11)[a]	P-value
Superficial calcium, n (%)	23 (100)	11 (100)	-
Maximum calcium length, mm	33.15 (15.62-40.20)	20.65 (14.78-25.10)	0.094
Maximum calcium arc, degree	299 (205-345)	142 (104-216)	0.001
Maximum calcium thickness, mm	1.24±0.23	1.04±0.25	0.029
Minimum lumen area, mm^2	1.64 (1.16-2.28)	2.26 (1.65-2.71)	0.217
Reference vessel area, mm^2	6.47 (5.08-8.20)	5.30 (5.11-6.92)	0.429
Diameter stenosis, %	52.76 (45.59-58.58)	66.29 (55.66-71.74)	0.038
Area stenosis, %	81.73 (80.06-83.37)	84.11 (82.44-86.80)	0.063

B, Post-stent

Variables	Poor stent expansion (n=23)[a]	Adequate stent expansion (n=11)[a]	P-value
Tissue prolapse, n (%)[b]	1 (4.3)	0 (0)	>0.999
Stent edge dissection, n (%)	0 (0)	0 (0)	-
Stent malapposition, n (%)[b]	13 (60.9)	1 (9.1)	0.011
Minimum stent area, mm^2	4.25 (3.96-5.62)	5.42 (4.60-6.77)	0.146
Reference vessel area, mm^2	8.02 (6.43-9.09)	5.90 (5.33-8.64)	0.217
Stent expansion, %	63.39±12.72	86.10±4.59	<0.001

[a]Represents the number of lesions. [b]Compared using Fisher's exact test. Data are presented as the number (%), mean ± standard deviation or median (interquartile range).

Table V. Univariate and multivariate logistic regression model of stent underexpansion.

A, Univariate analysis

Variables	β-coefficient	Odds ratio	95% CI	P-value
Age, years	0.133	1.143	1.044-1.297	0.013
Maximum calcium arc, degree	0.019	1.019	1.008-1.035	0.004
Diameter stenosis, %	-0.063	0.939	0.872-0.988	0.048

B, Multivariate analysis

Variables	β-coefficient	Odds ratio	95% CI	P-value
Age, years	0.159	1.173	1.036-1.438	0.042
Maximum calcium arc, degree	0.023	1.023	1.008-1.050	0.021

The inconsistency in the inclusion criteria among these studies may partially explain the different results observed. Furthermore, the present study proposed a novel calcium scoring system based on the aforementioned parameters, which displayed high accuracy in predicting the risk of stent underexpansion.

OCT confers superior improved capability compared with coronary angiography for the detection of calcium, with a sensitivity ranging between 95 and 96% and a specificity of 97% (22,23). In addition, compared with visual angiographic assessment alone, intracoronary OCT images can provide additional information on the parameters associated with the calcification severity of target lesions, such as maximum calcium arc, thickness, depth and longitudinal length (6). In the present study, the maximum calcium arc determined from the

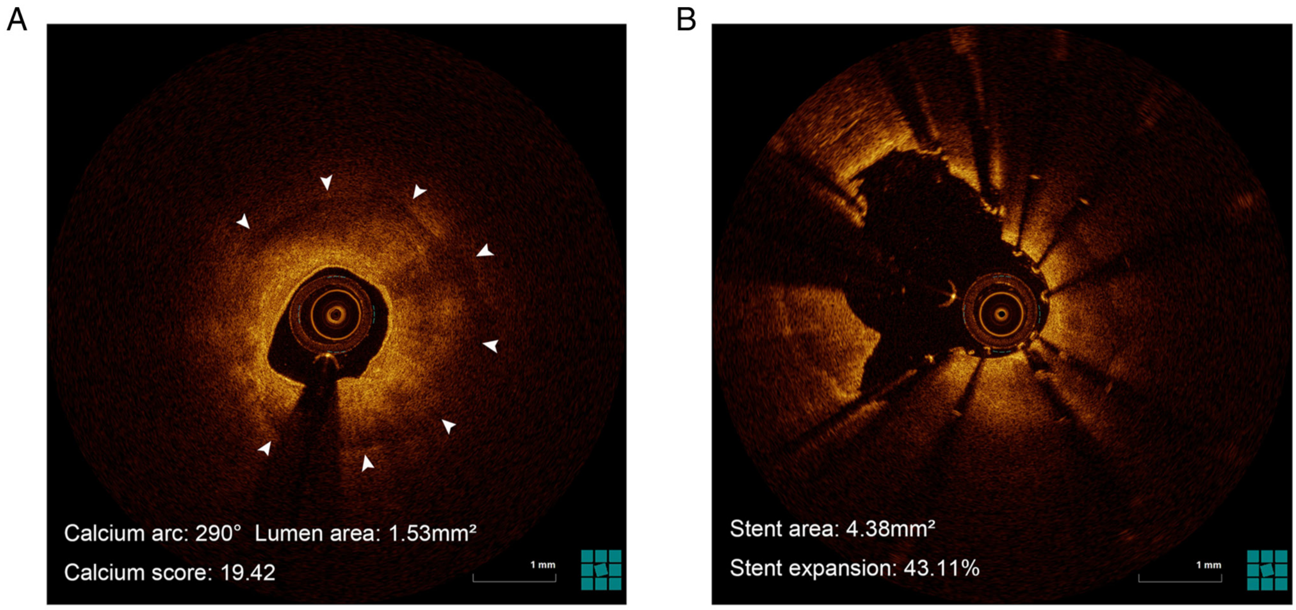

Figure 3. Representative OCT images. (A) Lesion manifested as severe calcified stenosis, which had a calcium arc of 290° (arrowheads) and a minimum lumen area of 1.53 mm^2 as determined on the pre-stent OCT image. The calcium score of the lesion was 19.42. (B) Following stent implantation, the final OCT image indicated poor stent expansion with a minimum stent area of 4.38 mm^2. OCT, optical coherence tomography.

OCT images was demonstrated to be a potential independent predictor of stent underexpansion, whereas parameters from QCA were not. These results highlighted the importance and value of intravascular imaging modality for severe calcified lesions in the interventional strategy-making process. The Society for Cardiovascular Angiography and Interventions position statement published in 2020 recommended that moderate and severe calcium observed on coronary angiography, as well as inadequate balloon expansion during lesion preparation before stent implantation, should be evaluated by intravascular imaging (24). In the present study, angiographically visible moderate and severe calcified lesions were found in 30 (88.2%) lesions. By contrast, the remaining four lesions, which showed mild calcification on angiography, had poor balloon expansion during lesion preparation. Therefore, OCT evaluation of all lesions was performed according to the recommendation in the aforementioned 2020 position statement.

The results of a previous study reported that for lesions with none/mild calcification the rate of major adverse cardiac events at 1-year is only 8.3%, whereas this increases to 14.6 and 17.7% for moderate and severe calcified lesions, respectively (25). Fujino *et al* (8) previously developed an OCT-based calcium scoring system to identify lesions, which may be at risk of stent underexpansion and benefit from plaque modification prior to stent implantation. In this previous study, only 29.7% of the patients enrolled had moderate and/or severe calcified lesions as assessed using angiography. Furthermore, the OCT characteristics of the patients tended to be relatively mild calcification. Patients treated with RA or scoring balloon were excluded. By contrast, in the present study 88.2% of the lesions had angiographically visible moderate and severe calcification. These two scoring systems were also compared. The present study's population with moderate and severe coronary calcification demonstrated that this newly-established system exhibited an improved performance compared with the widely-used Fujino *et al* (8) system in predicting the immediate therapeutic outcome of PCI. The comparison of predictive performance between the novel and the Fujino *et al* (8) system in a patient population with mild calcified plaques may be the aim of future studies.

It is noteworthy that the proportion of RA during PCI was significantly higher in patients with poor stent expansion, which may potentially be the result of lesion calcification being more severe in this group of patients. Furthermore, there was a discrepancy between groups with adequate or poor stent expansion in the present study. Compared with the patients who had adequate stent expansion, patients in the poor stent expansion group were significantly older. The maximum calcium arc and thickness were also larger in the poor stent expansion group. However, the variables showing significant difference between the two groups and potential confounding factors, such as maximum calcium length, were included into the univariate and multivariate logistic regression analyses, to limit the influence of this discrepancy and to ensure the accuracy of the results.

The present study also had several limitations. The present study was retrospective, where leaving the interventional strategy to the surgeons' discretion may have affected the stent expansion and the final analysis. In addition, the relatively small number of patients were enrolled, which made the conclusion drawn from the study weaker. There was also a lack of a specific cohort to validate the accuracy of the present calcium scoring system to predict stent underexpansion. Furthermore, as the OCT images were not read and analyzed by the same interventional cardiologist at different times, the intra-observer concordance for the assessment of the OCT data could not be assessed. Information regarding peri-procedural complications, such as coronary dissection or perforation and the balloon used for post-dilatation, was not available. Finally, the capability of the calcium scoring system to predict the long-term clinical outcome post-PCI in patients with moderate and severe calcified lesions remains to be elucidated.

In conclusion, the novel OCT-based calcium scoring system in the present study demonstrated a high accuracy for the prediction of the occurrence of stent underexpansion in patients with moderate and severe coronary calcification. However, the present system requires further validation in a larger cohort.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

CH and LY collected, analyzed and interpreted the patient data. ZX and HL contributed to collection and analysis of the data. YM and QL performed the analysis and interpretation of angiographic and OCT data. ML and HZ confirm the authenticity of all the raw data and revised the manuscript critically for important intellectual content. CL and JL designed the present study. YM, QL, ML, HZ and JL performed the operation. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The present study was approved by the Ethics Committee of Peking University People's Hospital (Beijing, China; approval no. 2018PHB154-01) and conducted according to the principles of the Declaration of Helsinki. Since this clinical study was a retrospective analysis of the information of previous cases, without direct contact with the subjects and subject privacy protection, the risk borne by the subjects was not greater than the minimum risk. The Ethics Committee of Peking University People's Hospital waived the requirement for informed consent.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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