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Original article

Cut-off value of strut-vessel distance for the resolution of acute incomplete stent apposition in the early phase using serial optical coherence tomography after cobalt-chromium everolimus-eluting stent implantation

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ABSTRACT

Objective: The purpose of this study was to identify a cut-off value to predict the resolution of incomplete-stent-apposition (ISA) after cobalt-chromium everolimus-eluting stent (CoCr-EES) implantation at early follow-up.
Background: To date, appropriate stent apposition at the acute period using intracoronary imaging has been recommended because persistent ISA is considered to be a risk factor for stent thrombosis. We examined the indices for resolving acute ISA. In particular, we determined the cut-off value for strut vessel distance (SV-distance) as visualized by optical coherence tomography (OCT) at 8 months after CoCr-EES implantation. However, the cut-off value of SV-distance for the earlier resolution of ISA is unclear.
Methods: A total of 95 cases and 103 stents were registered in the MECHANISM Elective substudy. The SV-distance was measured at the deepest site of the target malapposition and every 1 mm from the proximal edge to the distal edge of the mal-apposed area using OCT. Cut-off values for ISA resolution at 1 and 3 months were estimated by SV-distance using receiver operating characteristic analysis.
Results: The total number of analyzed struts was 14,418 at the 1-month follow-up and 11,986 at the 3-month follow-up. The optimal SV-distance cut-off values just after stent implantation to predict ISA resolution were 185 μm at the 1-month follow-up and 195 μm at the 3-month follow-up.
Conclusion: For resolution of ISA, SV-distance cut-off values of 185 μm at 1 month postimplantation and 195 μm at 3 months postimplantation can be used as the index of endpoint of the percutaneous coronary intervention.

Introduction

In recent years, percutaneous coronary intervention (PCI) has become the standard treatment for coronary disease. The use of a drug-eluting stent (DES), in which a drug that controls cell proliferation is coated onto a metallic stent, was developed to overcome stent restenosis, which was a major problem. It has been reported that the second-generation DES is endothelialized to the stent strut early and the polymer of second-generation DES plays a role in decreasing the inflammation of the vascular wall compared with the first-generation DES. The least amount of stent thrombosis occurs with the cobalt-chromium everolimus-eluting stent (CoCr-EES), which is used widely [1–3].

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The intravascular healing of a wound can be observed in detail, and the diagnostic accuracy for incomplete-stent-apposition (ISA) and late-acquired malapposition is markedly improved with optical coherence tomography (OCT) compared to intravascular ultrasound (IVUS) [4–8].

There are disagreements about the use of PCI under OCT guidance [9], although another study demonstrated that PCI with OCT guidance can be standardized using OCT imaging; therefore, this technique may improve clinical convalescence compared with IVUS-guided PCI [10–12].

Persistent ISA is considered to be a risk factor for stent thrombosis, and good apposition for the acute period using imaging has been recommended [13–15].

Furthermore, indices for resolving acute ISA in the chronic phase have been examined; in particular, the cut-off value of strut vessel (SV)-distance at 8 months after CoCr-EES implantation has been reported [16]. However, the SV-distance cut-off level for resolving ISA has not been clarified for early phase shorter than 8 months. The purpose of this study was to clarify the cut-off value to predict ISA resolution at the one-month and three-month follow-up in coronary artery disease (CAD) patients who were treated with a CoCr-EES by observing the persistent ISA after the CoCr-EES implantation.

Materials and methods

Study patients

The MECHANISM Elective (Multicenter Comparison of Early and Late Vascular Responses to a Everolimus-Eluting Cobalt-CHromium Stent and Platelet AggregatioN Studies in patients with Stable Angina Managed as Elective cases (Clinicaltrials.gov ID: NCT02014818, UMINID: UMIN000012616) study is a multi-center registry designed to elucidate early and late vascular responses to CoCr-EES for stable CAD patients using OCT. In the present study, 1- and 3-month cohorts were evaluated to elucidate early vascular responses to CoCr-EES in stable CAD patients using OCT. A total of 100 cases were included (50 groups to observe, and 50 groups to observe one month and three months later), and these cases were registered between November 2013 and August 2015 (Table 1).

Main results of the MECHANISM-Elective main study were published recently [17].

Exclusion criteria

Exclusion criteria were defined as follows: clinical difficulties at the 12-month follow-up, acute myocardial infarctions, cardiogenic shock, heart failure, left main lesions, reference vessel diameters of less than 2.0 mm or more than 4.5 mm, in-stent restenosis, chronic renal failure (serum creatinine of 2.0 mg/dl), hemodialysis, cancer patients who were expected to survive less than 2 years, elective surgeries requiring the cessation of dual antiplatelet therapy, pregnant patients or scheduled pregnancies, or a prior history of allergies to aspirin or clopidogrel.

OCT image acquisition

We performed OCT according to the Judkin's technique via the *trans*-radial or femoral approach, using a >6-French guiding catheter system. The ILLUMIEN or ILLUMIEN OPTISTM imaging system with the Dragonfly or Dragonfly JPTM imaging catheter (St. Jude Medical, St. Paul, MN, USA) was used in the present study. After the insertion of a 0.36-mm intervention guide wire, the imaging catheter was carefully advanced distal to the target lesion under fluoroscopic guidance. Motorized pullback OCT imaging was performed at a pull-back rate of 20 mm/s (ILLUMIEN), 18 mm/s (HD mode; ILLUMIEN OPTISTM), or 36 mm/s (ILLUMIEN OPTISTM; S mode) throughout the entire lesion [18]. Contrast medium was flushed continuously through the guiding catheter during the image acquisition period. Ringer's lactate or low-weight dextran fluids were available as needed according to each patient's clinical condition. Predilatation using a traditional balloon <2.0 mm was approved if the pre-intervention OCT imaging catheter was not passed distally from the lesion.

Table 1
Baseline characteristics of patients included in the present study.

	1-month cohort Patients (n = 50)	3-month cohort Patients (n = 50)	*p*-value
Age (years)	71 ± 8	70 ± 8	0.585
Male (%)	35 (70.0)	40 (80.0)	0.248
BMI (kg/m^2)	24.6 ± 3.6	24.5 ± 4.4	0.899
Diabetes mellitus (%)	28 (56.0)	30 (60.0)	0.685
Hypertension (%)	42 (84.0)	43 (86.0)	0.779
Dyslipidemia (%)	35 (70.0)	42 (84.0)	0.096
Smoker (%)	17 (34.0)	18 (36.0)	0.834
Clinical status			
Stable angina (%)	25 (50.0)	30 (60.0)	0.315
Silent myocardial ischemia (%)	25 (50.0)	20 (40.0)	
History of myocardial infarction (%)	6 (12.0)	15 (30.0)	0.027
Medication at the index procedure			
Clopidogrel (%)/Ticlopidine (%)	48 (96.0) / 2(4.0)	49 (98.0) /1 (2.0)	0.710
Statin (%)	35 (70.0)	38 (76.0)	0.499
Stent status			
Culprit vessel, LAD, RCA, LCx (n)	21 / 18 / 11	25 / 14 / 11	0.724
Implanted stent number (n)	1.2 ± 0.5	1.2 ± 0.4	0.651
Stent diameter (mm)	2.94 ± 0.39	2.88 ± 0.35	0.383
Stent length (mm)	24.8 ± 7.9	22.2 ± 7.5	0.145
Reference diameter (mm)	2.58 ± 0.48	2.54 ± 0.46	0.629
MLD (mm)	0.85 ± 0.30	0.80 ± 0.33	0.577
%diameter stenosis (%)	66.5 ± 12.2	68.1 ± 12.3	0.588

BMI, body mass index; LAD, left anterior descending artery; LCx, left circumflex artery; MLD, minimal lumen diameter; RCA, right coronary artery.

OCT image analysis

The OCT analysis was performed using LightLab OCT imaging proprietary software (LightLab Imaging/St. Jude Medical, Westford, MA, USA) by experienced multiple observers of the Iwate Core-analysis laboratory (ICAL), which has a central core laboratory staff that is independent of PCI. OCT image analysis was performed according to previous standard operation procedures (SOP) [17,19]. Quantitative OCT analyses were performed at every 1-mm interval for the assessment of lumen, stent, and intra-stent tissue area (stent area - lumen area). Intra-stent tissue thickness was measured from the lumen border to the center of the strut [20]. Struts with intra-stent tissue thickness less than 0 μm were defined as uncovered struts. A strut that was partially covered with tissue was classified as an uncovered strut. A strut with a maximum distance of >108 μm (metal thickness: 81 μm, coating thickness 7 μm, and axial resolution 20 μm) between its center reflection and the adjacent vessel surface was defined as a malapposed strut [21,22]. The SV-distance was measured at the deepest site of the target malapposition and every 1 mm from the proximal edge to the distal edge of the mal-apposed area. ISA was defined as the nonoccurrence of a stent strut crimping against the vessel wall, excluding the ISA which existed in the divergence department (Fig. 1). The corresponding malapposed struts were determined by comparing with the OCT image in the acute phase and the OCT image in the early phase side by side, and judging and examining from the position of the plaque and the position of the side branch.

We divided the plaque into the following four types: normal, lipid plaque, fibrous plaque, and calcified plaque, and we examined the residual rate of ISA per plaque. The plaque classification was made based on the main plaque behind the ISA plaque that was present in the ISA. To define the plaque, we followed the past consensus report [23]. Using the SV-distance cut-off values obtained for the 1-month and 3-month groups, struts were divided into the following two groups: those with an SV-distance equal to or greater than the cut-off value, and those with an SV-distance equal to or less than the cut-off value. Furthermore, the dominant plaques behind each ISA were examined, and the proportion of each plaque for which ISA remained was determined.

Late-acquired malapposition was defined according to past reports, i.e. as ISA that did not exist in the acute phase but occurred at follow-up [24] (Fig. 1). In this study, we examined the number of stents for which struts that did not develop ISA in the acute phase subsequently developed late-acquired malapposition after 1 and 3 months.

Statistical analysis

The data are presented as the mean ± SD. Differences in categorical data between the two groups were analyzed using the chi-square contingency test. In addition, comparisons of the means between two groups were analyzed using the Mann-Whitney *U* test. Differences were considered statistically significant when $p < 0.05$. All statistical analyses were performed with SPSS for Windows, version 21.0 (Chicago, IL, USA). The cut-off value was calculated using receiver operating characteristic (ROC) analysis.

Results

Patient characteristics

For the 1-month follow-up, one case was excluded because of a poor image. Ultimately, a total of 49 cases and 52 stents were registered. The total number of analyzed struts was 14,418, of which a total of 999 struts (14 %) displayed acute ISA. One month later, 708 struts (71 %) exhibited ISA resolution, and 291 struts (29 %) exhibited persistent malapposition (Fig. 2).

For the 3-month follow-up, four cases were excluded because of poor images. Ultimately, a total of 46 cases and 51 stents were registered. The total number of analyzed struts was 11,986, of which a total of 941 struts (7 %) displayed acute ISA. Three months later, 812 struts (86 %) exhibited ISA resolution, and 129 struts (14 %) exhibited persistent malapposition (Fig. 2). Thrombus within the ISA was not present in any of the 49 cases in the

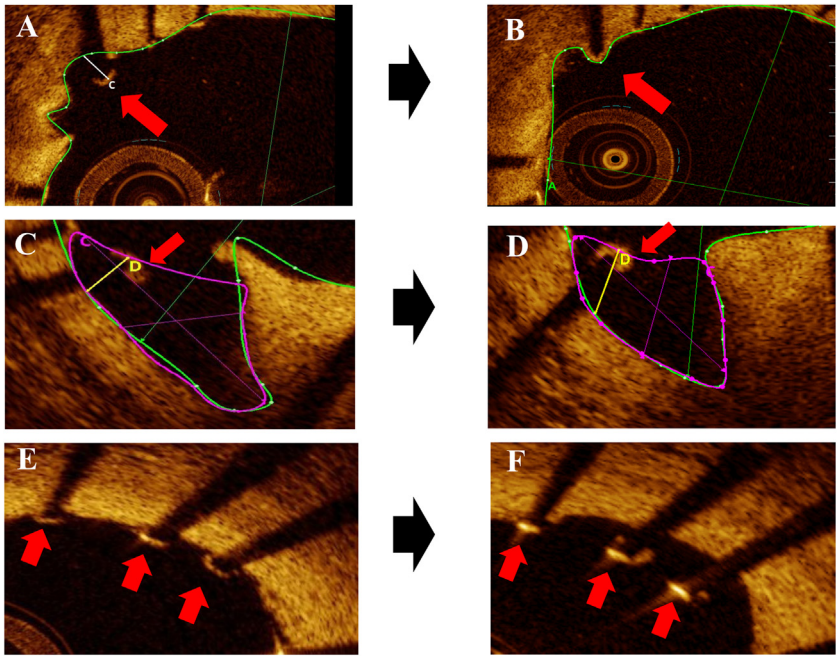

Fig. 1. Optical coherence tomography images showing the resolution of incomplete-stent-apposition (ISA) and persistent ISA. (A, C) ISA in the acute phase. (B) Resolution of ISA at follow-up. (D) Persistent ISA at follow-up. (E, F) Representative image of late-acquired malapposition. An apposed strut just after stenting caused malapposition at follow-up.

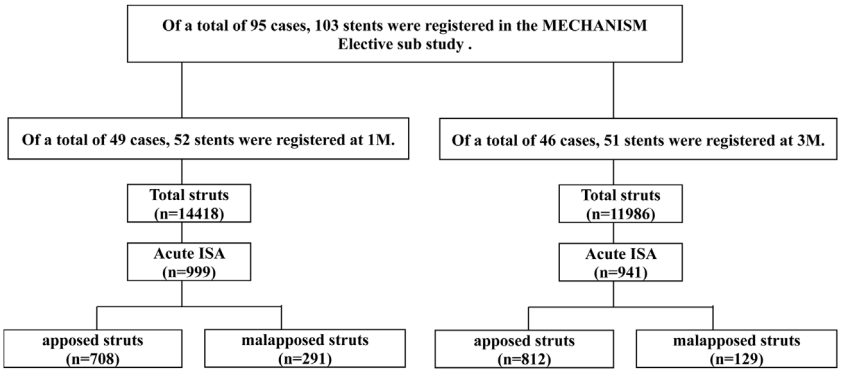

Fig. 2. Study patients. In this study, one case was excluded because of a poor image at the 1-month follow-up. In this study, four cases were excluded because of poor images at the 3-month follow-up.
ISA, incomplete-stent-apposition.

1- month group and was present in only 2 out of 46 cases in the 3-month group.

Incidence of the ISA resolution in each quartile of SV-distance

SV-distance was classified into quartiles, and the ISA resolution rate was calculated. For both the 1-month and 3-month groups, the ISA resolution rate decreased as SV-distance increased (Fig. 3).

ROC curve

The optimal cut-off value for SV-distance at the one-month follow-up just after the stent implantation to predict ISA resolution estimated by the ROC analysis was 185 μm. Sensitivity was 64.3 %, and specificity was 68.6 %. Moreover, the 95 % CI was 0.682 to 0.752, and the area under the curve was 0.717 (Fig. 4). The optimal cut-off value of the SV-distance at the three-month follow-up just after the stent implantation to predict ISA resolution estimated by the ROC analysis was 195 μm. Sensitivity was 70.5 %, and specificity was 73.0 %. Moreover, the 95 % CI was 0.723 to 0.811, and the area under the curve was 0.767 (Fig. 4).

Rate of persistent ISA on each plaque

The percentage of persistent ISA at the follow-ups was highest for the calcified plaques, regardless of SV-distance (Fig. 5). In the 3-month group, the ISA survival rate markedly decreased in plaques with an SV-distance below the cut-off value (Fig. 6). For calcified plaques of the 1-month and 3-month groups that had SV-distances greater than the cut-off value, the ISA survival rate was significantly higher compared with that of other plaques.

Discussion

In the present study, we examined the SV-distance cut-off value that best predicted the resolution of ISA at 1 and 3 months. These cut-off values were shown to be 185 μm and 195 μm, respectively. In addition, when the SV-distance was greater than or equal to the cut-off value, the ISA residual rate on each plaque was significantly higher in the former and the latter in the calcified plaque.

SV-distance

Recent reports have revealed that malapposition is the most common cause of very late stent thrombosis after DES deployment [25]. It has also been reported that delayed healing in vessels is involved in the formation of thrombus [26].

In a previous OCT study, the size of ISA was determined to naturally decrease even if ISA existed, and it was shown that the struts may completely appose. After the implantation of a CoCr-EES or zotarolimus-eluting stent (ZES), the SV-distance at which ISA disappears in the chronic phase of 6–13 month has been reported to be less than 270 μm [27].

It has been reported that ISA remains in 26 % of CoCr-EES and 38 % of sirolimus-eluting stents (SES) in 8–12 months of follow-up surveillance. Compared to the 1 st generation SES, the 2nd generation CoCr-EES has a high rate of resolution of acute ISA, suggesting its superiority in promoting intravascular healing [28]. Moreover, Inoue et al. reported that the SV-distance cut-off value for ISA resolution at 8 months after CoCr-1EES implantation was less than 380 μm [16]. In this study, the SV-distance cutoff values of the 1-month and 3-months groups were similar. This finding

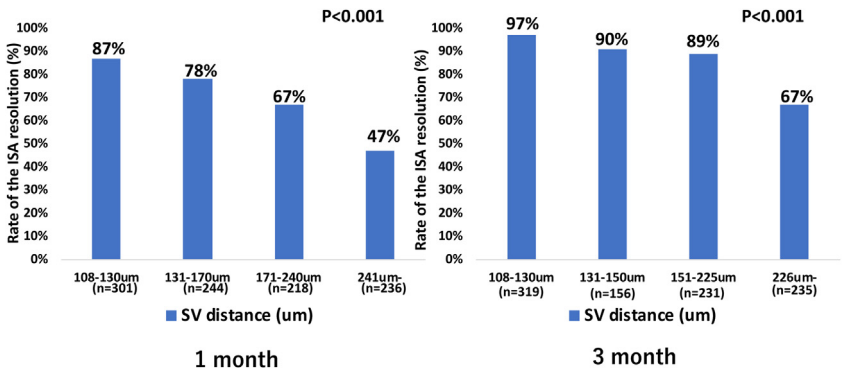

Fig. 3. Incidence of ISA resolution in each SV-distance quartile. SV-distance was classified into quartiles, and the ISA resolution rate was calculated. For both the 1-month and 3-month groups, the ISA resolution rate decreased as SV-distance increased. ISA, incomplete-stent-apposition; SV, strut vessel.

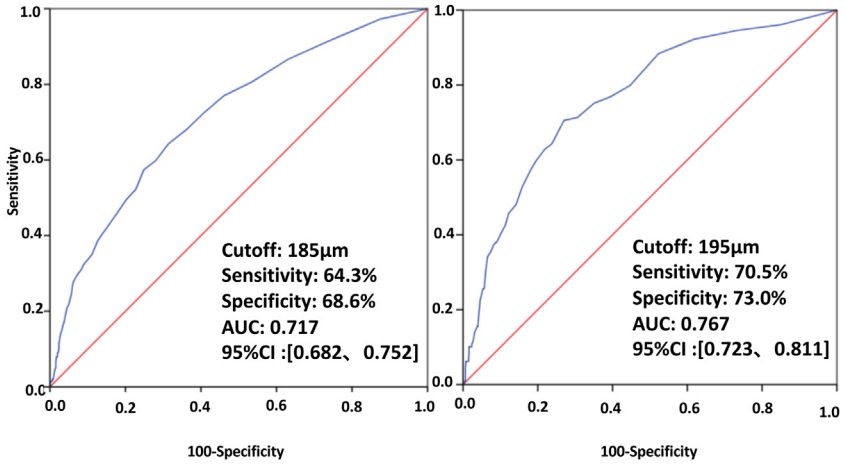

Fig. 4. ROC curve for cut-off value of the SV-distance. The optimal cut-off value of the SV-distance just after the stent implantation to predict ISA resolution estimated by the ROC analysis was 185 μm. Sensitivity was 64.3 %, and specificity was 68.6 %. Moreover, 95 % CI was 0.682–0.752, the area under the curve was 0.717 at the 1-month follow-up. The optimal cut-off value of the SV-distance just after the stent implantation to predict ISA resolution estimated by the ROC analysis was 195 μm. Sensitivity was 70.5 %, and specificity was 73.0 %. Moreover, the 95 % CI was 0.723-0.811, and the area under the curve was 0.767 at the 3-month follow-up.
CI, confidence interval; ISA, incomplete-stent-apposition; ROC, receiver operating characteristic; SV, strut vessel.

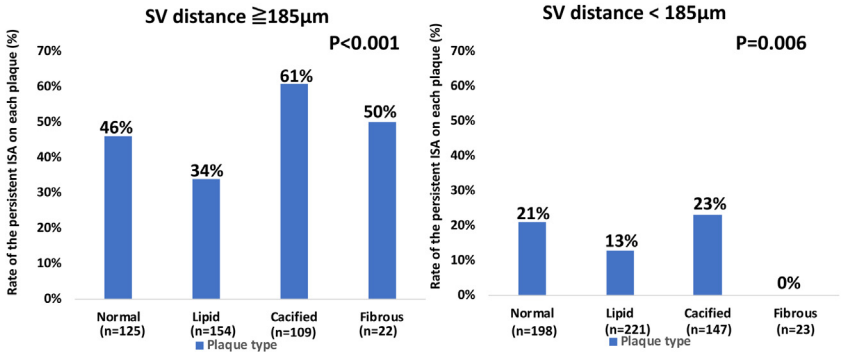

Fig. 5. Incidence of persistent ISA at 1 month on each plaque type. (a) Plaques with an SV-distance greater than or equal to 185 μm. (b) Plaques with an SV-distance less than 185 μm. The percentage of persistent ISA at the follow-ups was highest for the calcified plaques, regardless of SV-distance.
ISA, incomplete-stent-apposition; SV, strut vessel.

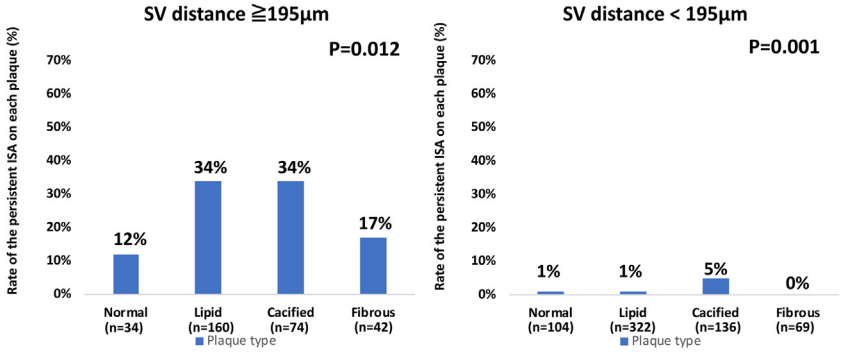

Fig. 6. Incidence of persistent ISA at 3 months on each plaque type. (a) Plaques with an SV-distance greater than or equal to 195?μm. (b) Plaques with an SV-distance less than 195?μm. In the 3-month group, the ISA survival rate markedly decreased in plaques with an SV-distance below the cut-off value.
ISA, incomplete-stent-apposition; SV, strut vessel.

suggests that there is no difference in intravascular healing between 1 and 3 months, suggesting that within the 3-month period, the acute intravascular healing is nearly complete within 1 month. Compared with 3-month dual antiplatelet therapy (DAPT) and 12-month DAPT, it is reported that there is no significant difference in stent-related events, thus it is recommended to cease DAPT in a short period in patients with chronic CAD [29]. Currently, it is recommended in the European Society of Cardiology guidelines to determine the duration of DAPT using the PRECICE DAPT score after stent deployment [30]. The patient's clinical background, including age, hemoglobin, renal function, and presence of past bleeding events are evaluated. The information regarding SV-distance in this study may provide supplementary guidance for determining the DAPT period.

Cause of ISA resolution

ISA resolution is thought to be due to fibrin aggregation and neointimal healing. Lee et al. reported that neointimal healing is a factor for ISA resolution [31]. In another study that used OCT, various tissue forms (homogeneous, layered, crenellated, etc.) have been reported behind the stent where the ISA was resolved. However, undoubtedly, several tissue forms appear in their follow-up OCT image because image acquisition was preformed not uniformly but between 6 months and 13 months [27]. Pathologically, stent strut coverage has been reported to involve an initial thrombus and fibrin aggregation followed by tissue replacement to the neointima [32]. Neointimal coverage of the struts has also been proven pathologically [33]. Moreover, it has been reported that fibrin thrombus aggregation is observed at the struts of the ISA lesion [34]. To summarize the above, it is presumed that fibrin thrombus aggregation occurs at the ISA site in the early stage and that ISA is eliminated by replacing the thrombi with tissues. In this study, although the characteristics of the tissue behind the apposed strut visualized by OCT in the convalescent phase were not evaluated, it is thought that ISA resolution occurs by the same mechanism.

Relationship between ISA and prognosis

To date, there have been reports that ISA is both related to prognosis and not related to prognosis. There have been several reports supporting the former, as follows: 1) ISA was shown to be related to the occurrence of late onset stent thrombosis, and the predictor of late stent thrombosis was determined to be the length of the uncovered strut [15]; 2) ISA was shown to be a risk factor for in-stent thrombosis and a predictor of adverse events [35]. These reports indicate that to reduce the risk of late stent thrombosis, good stent apposition in the acute phase by OCT is important. On the other hand, although there is a report demonstrating that the latter major adverse cardiovascular events and ISA are not related, this report has several problems [36,37]. In particular, in the study by Wang et al., the accumulated event incidence rates of the ISA-present group and the ISA-absent group were equal, and propensity score matching was not performed, despite the significant minimal stent area (MSA) size being large [37]. As described above, there is no clear conclusion about the relationship between the presence or absence of ISA and prognosis. By measuring the SV-distance by OCT in the acute phase, however, it is possible to obtain a certain stent apposition in a short time. The resolution of ISA in a short period will lead to early stent covering, resulting in risk avoidance.

Late acquired malapposition

Late-acquired malapposition is defined as ISA that was not acknowledged in the acute phase and newly occurs during the recovery period [24]. Late-acquired malapposition is accompanied by the disappearance of thrombus that was generated in the acute phase and the pathologic dilatation of the coronary artery with drugs and polymers (vascular remodeling), which may cause intrastent thrombosis and restenosis [24]. In this study, late-acquired malapposition occurred in 28.8 % of the 1-month group and 21.8 % of the 3-month group. Inoue et al. reported that the incidence of late-acquired malapposition after 8 months was 11.4 % [16]; compared to our study, the incidence of late-acquired malapposition was low. Based on these data, it is estimated that the occurrence of late-acquired malapposition decreases from 3 months to 8 months. This phenomenon is thought to be due to the elapse of time after the stent implantation; 80 % of the drugs are released in 30 days, and the drugs completely disappear in 120 days. Moreover, the affinity with the polymer leads to a decreased inflammatory response. In addition, it has been reported that late-acquired malapposition can cause delayed thrombosis after DES implantation [13]. It has also been reported that the incidence of stent thrombosis at 9 months after CoCr-EES implantation is lower than that of SES (CoCr-EES 5.0 % VS SES 34.3 %, $p < 0.001$) [29].

In this study, the number of thrombi with malapposition and late-acquired malapposition was very small. As reported by Baber et al., the risk of thrombosis is lower with CoCr-EES [38]. This finding was thought to be because CoCr-EES includes a thin stent strut and a fluoropolymer with antithrombogenicity, compared with other stents [39].

The residual rate of ISA per plaque

After classifying the plaques into four groups based on the previously obtained SV-distance cut-off values, the plaques were further divided into two groups, and we determined the rate of persistent ISA of each group. The incidence of persistent ISA in both groups was higher for calcified plaques compared with other plaques. Generally, for calcified plaque, DES are unevenly expanded and often malfunctioning, resulting in ISA, which causes stenosis within the stent and thrombosis. These findings suggest that for vascular lesions with many calcified plaques, good dilation must be obtained. ISA resolution is caused by endothelial cell proliferation and filling by neointimal proliferation, which ends within 2–6 weeks. There are reports that ISA remains due to the inhibition of neointimal proliferation by calcified plaque [40]. Inoue et al. similarly classified plaques into two groups according to the cut-off value of SV-distance at 8 month and examined the rate of persistent ISA on each plaque. However, for plaques with an SV-distance greater than the cut-off value, there was no significant difference in the rate of persistent ISA regardless of the type of plaque [16]. In our study, the incidence of remaining ISA for plaques with an SV-distance greater than the cut-off value was significantly higher for calcified lesions in both the 1- and 3-month groups. This discrepancy occurs likely because in the study by Inoue et al. there were no calcified lesions with an SV-distance of 380 μm or higher, and a comparison between lipid and fibrous was made.

Study limitations

There are several limitations inherent to this study. First, the patient number was small. However, the cut-off values we obtained are thought to be highly accurate because they were determined from high-resolution images visualized by OCT. Second, the present study was a post-hoc analysis, not a prospective study. Third, the results may be not appropriate for other stents because these data were obtained from patients treated with CoCr-EES. The cut-off values for other stents will need to be analyzed separately in the future. Fourth, a prognostic evaluation of the patients in the study was not performed. Further studies are warranted to evaluate patient prognosis based on the presence or absence of ISA by OCT. Finally, we did not evaluate the characteristics of the tissue behind the apposed strut with OCT or pathologically, thus OCT and pathological evaluations of the ISA sites are required.

Conclusions

To predict the resolution of ISA, SV-distance cut-off values of 185 μm for 1 month and 195 μm for 3 months can be used as the index of endpoint of the PCI.

Conflict of interest

Itoh T: Lecture honoraria (Daiichi Sankyo, Abbott Vascular Japan). Ootake H: Lecture honoraria (Abbott Vascular Japan).

Morino Y: Research grant (Daiichi Sankyo), Lecture honoraria (Daiichi Sankyo, Abbott Vascular). Shinke T: Research grant (Daiichi Sankyo), Lecture honoraria (Daiichi Sankyo, Abbott Vascular). The other authors do not have any conflicts of interest or financial disclosures.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.jjcc.2019.12.006.

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