Study On Coronary Dissection Complication Caused by Uneven Rotational Atherectomy Due To Guidewire Bias for Severe Calcified Lesions

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Abstract

BACKGROUND

In the treatment of coronary calcification by rotational atherectomy (ROTA), guidewire bias is often considered to lead to procedure associated coronary dissections or perforations. However, the actual meaning of guidewire bias is unclear, though it usually refers to the cross-section location of the intravascular imaging (IVI) catheter in the coronary artery.

OBJECTIVES

This study tentatively explores the quantitative criteria in optical coherence tomography (OCT) imaging of guidewire bias which may cause ROTA induced coronary dissection.

METHODS

A total of twenty-one patients with severe calcified coronary lesions who has undergone ROTA treatment were enrolled in our study. These patients were detected by OCT successfully pre- and post-ROTA. All the observational coronary segments were analyzed cross-sectionally at every mm interval after manual coregistration of OCT imaging pre- and post-ROTA. ROTA related coronary dissection was the primary endpoint.

RESULTS

A total of 388 OCT cross-sectional images were effectively measured and analyzed for distribution and characteristics of plaque and OCT catheter location pre-ROTA, and the presence or absence of coronary dissections post-ROTA after manual coregistration. According to the receiver operating characteristic (ROC) analysis, distance from the center of OCT catheter to media at the bias direction (D_{cmb}) (area under the curve (AUC): 1.000, p<0.001, 95% confidence intervals (CI): 0.999 to 1.000) and touch angle (AUC: 0.988, p<0.001, 95%CI: 0.968 to 1.000) had a higher correlation with ROTA-related coronary dissection with the corresponding cutoff value of 0.720mm and 98.2º significantly.

CONCLUSIONS

D_{cmb} and touch angle detected by OCT are two very valuable and convenient independent predictors of ROTA-related coronary intimal dissections caused by guidewire bias.

Background

Guidewire bias is an inevitable scenario during percutaneous coronary intervention (PCI), especially when the target vessel is tortuous or angulated. However, it is difficult to accurately describe and quantitative analyze this common phenomenon only through coronary angiography, which will significantly affect the safety and efficacy of PCI procedure such as rotational atherectomy (ROTA) for severe calcified lesions. With the development of the application of intravascular imaging (IVI) technology in PCI, the understanding of guidewire bias is becoming more and more in-depth by IVI (including optical coherence tomography (OCT) and intravascular ultrasound (IVUS)).[1] There are however no in-depth studies on how guidewire bias affects PCI, especially on calcified lesions. Although rotational atherectomy (ROTA) therapy is one of the more effective treatments for moderate and severe coronary arterial calcified lesions, the current concept of treating coronary calcified lesions by ROTA is modification rather than debulking.[2-4] Wire bias may be a negative factor in ROAT treatment.[5] A previous small number observational study showed that the effect of ROTA burr on the four vertical directions of the vascular cross section was different due to the guide wire bias. Based on the IVUS findings, the reduction of intima to media thickness on the vertical direction (IVI contact point) is significantly greater than that in the horizontal direction.[6] Deep ROTA procedure can even lead to coronary dissection or perforation.[7-9]

Although the concept that guidewire bias can lead to a significant increase in ROTA-related complications of dissection is not new, quantitative indices to support that belief have yet to be published. Even in the current era of popular IVI guiding PCI, the concept of guidewire bias that can easily lead to ROTA-related dissection is still in its infancy. The purpose of this study was to retrospectively analyze OCT data of patients with moderate to severe coronary calcification pre- and post-ROTA treatment, and to explore the true meaning of guidewire bias that may easily lead to ROTA related coronary dissections.

Methods

Study design. This was a retrospective, single center, observational study to explore whether guidewire bias detected by OCT could easily lead to ROTA related coronary dissections. The quantitative criteria of guidewire bias are further analyzed by comparing OCT data and coronary angiography pre- and post-ROTA procedure using post manual co-registration correction.

From October 2012 to July 2021, a total of 717 cases of ROTA were screened in the database of Nanjing First Hospital (Nanjing Medical University), among which 21 patients received OCT detection pre- and post-ROTA procedures. Exclusions included records that indicated: lesion preparation with predilatation before OCT detection, poor quality of OCT images that could not measure precisely, coronary angiographic analysis that did not clarify ROTA burr movement segment, and cases where OCT data was missing pre- or post-ROTA. Finally, a total of 388 pairs of OCT cross-sectional images were measured and analyzed at 1mm intervals. This retrospective study was approved by the institutional review board of Nanjing First Hospital (Nanjing Medical University) and written informed consent was obtained from all patients and all treatment methods were performed in accordance with the ACC/AHA/ESC guidelines or consensus regulations.

Coronary angiography analysis. Quantitative coronary analysis (QCA) was not important in this study because the analysis was based on OCT cross-sectional data rather than changes in coronary artery diameter. The aim of coronary angiography analysis is to clarify the trajectory and range of ROTA burr movement segments and to maintain consistency with OCT analysis.

OCT images acquisition. OCT images were acquired after nitroglycerin intra-coronary injection into target coronary artery with moderator or severe calcified lesions pre- and post-ROTA. OCT image checking with both ILUMIEN OPTIS and C7-XR (Lightlab Imaging Incorporated, Westford, MA) was performed using a 2.7F (Dragonfly OPTIS or Dragonfly Duo imaging catheter, Westford, MA) catheter automatic pullback at a speed of 36mm/sec with continuous contrast injection (3-4 ml/s). Due to lesion obstruction, not all calcified lesions’ segments could be detected by OCT before ROTA.

Therefore, in this study, if the OCT catheter passed through the whole ROTA segment before ROTA operation and the image quality was high enough for analysis, the farthest point of the ROTA burr movement recorded by coronary angiography guidance was the distal mark for analysis. If the OCT catheter could not pass through the whole ROTA segment before ROTA operation, the endpoint for analysis was marked by the farthest point of the OCT catheter could reach before ROTA operation. The starting point of analysis was the beginning of the ROTA operation site as shown by coronary angiography.

OCT images analysis. All OCT data (pre- and post-ROTA) and coronary angiography were analyzed post manual co-registration based on range of motion of the ROTA burr according to coronary angiography or range of OCT detection pre-ROTA. Off-line OCT images were analyzed cross-sectionally at every mm interval after manual coregistration of OCT imaging pre- and post-ROTA by Lightlab OPTIS, E. 4 software (Lightlab Imaging Incorporated, Westford, MA). Calcification in OCT was defined as a signal-poor and heterogeneous region with sharply delineated near and far boundary.[10–12] Coronary dissections are defined as rims of tissue protruding into the lumen,[13,14] and were classified into five categories (similar to the IVUS classification): intimal: limited to the intima or plaque, and not extending to the media; medial: extending into the media; adventitial: extending through the external elastic membrane (EEM); intramural hematoma: an accumulation of flushing media within the medial space, displacing the internal elastic membrane inward and EEM outward; intra-stent: separation of neointimal hyperplasia from stent struts, usually seen only after treatment of in-stent restenosis (the last category is also outside the scope of this study).[15] Intimal dissection induced by ROTA procedure only met the requirements of this study.

Pre-/post-ROTA OCT images and coronary angiography were manually coregistered by fiduciary side branch based on ROTA burr route before measurement. Each measurement index of OCT at each cross section of corresponding segment in this study was defined as follows: at each cross section, the center point of the OCT catheter is connected to the center point of the vessel in a straight line. The quadrant of OCT catheter bias in the fan-shaped face with the vascular center as the dot is defined as the bias quadrant (Figure 1) as per the center line, and then each index was measured. 1) Distance from the center of OCT catheter to intima at the bias direction (D_{cib}); 2) Distance from the center of OCT catheter to intima at the opposite side of the bias (D_{cio}); 3) Distance from the center of OCT catheter to media at the bias direction (D_{cmb}); 4) Distance from the center of OCT catheter to media at the opposite side of the bias (D_{cmo}) (Figure 1); 5) Touch angle: the arc of contact between OCT catheter and the intima of coronary artery (Figure 1,2); 6) Luminal area (LA): the area bounded by the luminal border; 7) Minimal luminal diameter (M_{in}LD): the shortest length through the center point of the lumen; 8) Maximal luminal diameter (M_{ax}LD): the longest length through the center point of the lumen; 9) Lumen eccentricity (LE): defined as (M_{ax}LD-M_{in}LD)/ M_{ax}LD; 10) EEM cross sectional area (CSA); 11) Average vessel diameter (AVD): defined as (minimal EEM diameter + maximal EEM diameter)/2. All the image data were analyzed off-line for ROTA burr movement segment by two independent professional analysts who were blinded to the other analyses as well as to the ROTA procedure and corresponding coronary angiographic result. Finally, OCT data were compared cross section by cross section to confirm the relationship of wire bias to ROTA-related coronary dissection by OCT detection.

Statistical analysis. Before all data were statistically analyzed, intra- and inter-observer variability of the images analysis were assessed by evaluating 50 randomly selected slides of cross section OCT data. Consistency test was performed by Kappa statistics for categorical variable or intraclass correlation coefficients (ICC) for continuous variables. Categorical variables were expressed as frequencies and were compared by chi square statistics or Fisher exact test as appropriate. Continuous variables were expressed as the mean ± standard deviation for the normal distribution by the Kolmogorov-Smirnov test or shown as median and first and third quartiles and compared by the

Mann-Whitney U or Kruskal-Wallis test with post hoc analysis by Dunn-Bonferroni test for non-normally distributed continuous variables. After univariate correlation analysis, for identification of potential correlations between variables, receiver operating characteristic (ROC) analysis was used to determine the discriminatory capability as an area under the curve (AUC) with the optimal cutoff value using Youden's index (the maximum value of [sensitivity + specificity - 1]). All tests were 2-tailed with a 0.05 significance level. All statistical analyses, except Passing-Bablok regression, were performed with SPSS 18.0 (IBM, Armonk, New York) and Windows version R 4.0.5 software (https://www.r-project.org/).

Results

Consistency test between inter- and intra-observer variability for OCT images measurement. There was very good inter- and intra-observer agreement for the OCT measurement of D_{cib} (ICC: 0.996,0.998), D_{cio} (ICC: 0.990,0.999), D_{cmb} (ICC: 0.992,0.992), and D_{cmo} (ICC: 0.957,0.997); and agreement for the assessment of coronary intimal dissection by OCT detection (Kappa: 0.878,0.878), plaque characteristics (with or without calcification) at wire bias direction (Kappa: 0.961,0.985).

Patients' clinical characteristics and basic coronary lesions' location. The baseline clinical and coronary disease characteristics were summarized in Table 1. Average patient age was 71±7.20 and 76.2% were male. The prevalence of chronic kidney disease was only 4.7%, and the most common target vessel for ROTA treatment was the left anterior descending artery (LAD) about 81.0% and located at proximal segment about 42.9% (Table 1).

Table 1
Baseline clinical and coronary disease characteristics patients

Variables	**N=21**
Age, years	71±7.20
Male, *n* (%)	16,(76.2)
Body mass index, kg/m^2	24.11±3.97
Diabetes mellitus, *n* (%)	4,(19.0)
Hypertension, *n* (%)	14,(66.7)
Hyperlipidemia, *n* (%)	12,(57.1)
Current smoking, *n* (%)	8,(38.1)
Chronic kidney disease, *n* (%)	1,(4.7)
Previous myocardial infarction, *n* (%)	3,(14.3)
Clinical presentation	
STEMI, *n* (%)	2,(9.5)
Non-STEMI, *n* (%)	0,(0.0)
Unstable angina, *n* (%)	13,(61.9)
Left ventricular ejection fraction, %	62.10±5.32
Total cholesterol, mmol/L	3.54±0.69
Low-density lipoprotein, mmol/L	1.86±0.49
High-density lipoprotein, mmol/L	1.07±0.37
eGFR, ml/min/1.73 m^2	86.23±25.09
Target vessel	
LAD (%)	17,(81.0)
RCA (%)	3,(14.3)
LCx (%)	1,(4.7)
Lesion location	
Proximal	9,(42.9)
Middle	11,(52.4)
Distal	1,(4.7)
Reference vessel diameter	3.18±0.47
Final burr size	1.65±0.20
BTV	0.53±0.08

Variables	N=21
Values are median (interquartile range) or % (number of observations/total number of patients). BTV, burr to vessel; eGFR, estimated glomerular filtration rate; EI, expansion index; IVUS, intravascular ultrasound; LAD, left anterior descending artery; LCx, left circumflex; RCA, right coronary artery; STEMI, ST-segment elevation myocardial infarction.	

Measurement of cross-sectional parameters of OCT catheter bias. A total of twenty-one segments in 21 patients were enrolled in analysis for OCT images, finally 388 pairs of slides of cross-sectional parameters of OCT measurement were compared post manual coregistration pre- and post-ROTA guided by angiographic ROTA range. Finally, ROTA-related coronary intimal dissections were found in 56 layers post-ROTA from OCT data. Given that most univariate correlation analysis for potential parameters may indicate wire bias degree. D_{cib}, D_{cio}, D_{cmb}, D_{cmo}, final burr size, touch angle, M_{in}LD and M_{ax}LD may correlate with ROTA-related coronary intimal dissection, ROC analysis was performed to determine potential relationships involved and further test the discriminatory power of this procedure. The AUC, sensitivity and specificity were calculated by R package “pROC”. DeLong’s test was also performed for optimum predictive index of ROTA-related dissection with two correlated comparative ROC curves. The AUC of D_{cmb} and touch angle were significantly higher than that of other parameters (p<0.001). In terms of clinical convenience, D_{cmb} and touch angle were the best parameters which could predict ROTA-related coronary intimal dissection (Table 2, Figure 2).

Table II. Univariate and ROC analysis for correlation between the variables and ROTA-related coronary intimal dissection

variables	Univariate analysis		ROC analysis							
	r	p	AUC	95%CI		Sensitivity	Specificity	Cut-off value	p	YI
D_{cib}	-0.407	<0.001	0.942	0.920	0.964	86.4%	95.4%	0.435	<0.001	0.828
D_{cio}	0.139	0.006	0.664	0.592	0.737	67.9%	65.1%	1.125	<0.001	0.330
D_{cmb}	-0.625	<0.001	1.000	0.999	1.000	98.8%	100.0%	0.720	<0.001	0.988
D_{cmo}	0.169	0.001	0.661	0.584	0.738	50.0%	80.7%	2.875	<0.001	0.307
Final burr size	-0.133	0.009	0.581	0.510	0.652	-	-	-	0.053	-
Touch angle	0.912	<0.001	0.988	0.968	1.000	94.6%	98.2%	98.2	<0.001	0.946
M_{in}LD	-0.104	0.040	0.540	0.459	0.621	-	-	-	0.343	-
M_{ax}LD	-0.119	0.019	0.566	0.495	0.637	-	-	-	0.112	-

AUC, area under the curve; CI, confidence intervals; D_{cib}, distance from center of OCT catheter to intima at the bias direction; D_{cio}, distance from center of OCT catheter to intima at the opposite side of the bias; D_{cmb}, distance from center of OCT catheter to media at the bias direction; D_{cmo}, distance from center of OCT catheter to media at the opposite side of the bias; $M_{ax}LD$, maximal luminal diameter: the longest diameter through the center point of the lumen; $M_{in}LD$, minimal luminal diameter: the shortest diameter through the center point of the lumen; ROC, receiver operating characteristic; ROTA, rotational atherectomy; YI, Youden's index;

The coincidence rate of ROTA-related coronary intimal dissection radial distribution involving OCT catheter bias quadrant pre-ROTA was 100% by comparing OCT data pre- and post-ROTA. Further analysis showed that the bias of the OCT catheter to the coronary dissection (subintimal) was 100% post-ROTA (Figure 2).

Discussion

The main findings in our retrospective study were as follow: 1) As an OCT indicator for the reaction of guidewire bias, D_{cmb} and touch angle are two very valuable and convenient independent predictors of ROTA-related coronary intimal dissections; 2) The OCT catheter bias quadrant pre-ROTA was highly consistent with the quadrant where the ROTA-related coronary intimal dissection was present; 3) OCT catheters are always trapped beneath the ROTA-related dissection.

The operation of ROTA is accomplished by pushing a burr in and out of the calcified lesion along the special guide wire.[16,17] Due to the principle of differential cutting and friction, it is generally believed that ROTA only ablate inelastic fibrocalcific plaques while sparing adjacent elastic tissue that deflects away from the ablating burr.[18,19] However, the ROTA burrs may have ablative effect on the substance in contact.[20–22] Guidewire bias position in an angled or tortuous coronary artery is inevitable: a divergence from the central axis of the vessel or the lumen and may result in ablation on the bias side of the coronary wall occurs, iatrogenic injury to intima or media may result and deeper cutting action could lead to more complications: such as dissection or even perforation).[5,21,23]

In our retrospective study, we analyzed for the first time the quantitative indicators that guide wire bias caused the motion path bias of ROTA burrs and further led to the occurrence of iatrogenic coronary dissection. Guidewire position bias in an angled or tortuous coronary artery is inevitable; a divergence from the central axis of the vessel or the lumen and may result in ablation on the bias side of the coronary wall. If bias to relatively normal coronary wall occurs, iatrogenic injury to intima or media may result and deeper cutting action could lead to more complications: such as dissection or even perforation).[5,21,23] no quantitative data have been reported before. In this study, we used a novel method to analyze the distribution characteristics of coronary cross-sectional plaques, location of OCT catheters, and their relationship with the coronary dissection post-ROTA by IVI technique at 1mm intervals after manual co-registration pre-, post-ROTA and angiographic data. Although D_{cmb} and touch angle could predict ROTA-related dissection to the same extent, the simple and clinically feasible measurements were D_{cmb} and touch angle indicators, the cut-off value of D_{cmb} was 0.720mm which including the radius of the OCT catheter (0.45mm) and the thickness of the intima and part of the media and of touch angle was 98.2º.

Shoter D_{cmb} resulted in higher ratios of ROTA-related coronary intimal dissection. Small value D_{cmb} often indicates the OCT catheter is biased to and in contact with the coronary vessel wall.

Touch angle is another novel finding which indicates the closeness of OCT catheter contact with a coronary wall. The bigger the touch angle, the closer to contact; the presence of OCT catheter entrapment in the coronary wall (like a finger pressure sign) is often indicative of relatively soft vessel wall at the bias site (usually normal blood vessel segments rather than calcified lesions), as well as a strong compression force of OCT catheter against the vessel wall.

Sometimes media is not easy recognized at the bias site without a large plaque burden. Touch angle, which can be measured easily, is a good alternative index for avoiding ROTA-related complications (Figure 2).

The following four points must be understood when we use the guidewire bias idea to infer the point of view of ROTA bias:

1) Guidewire bias is the starting point but cannot be quantified and guided to optimize ROTA precisely.

2) Catheter bias can be quantified by IVI checking along a PCI guidewire of 0.014 inch, but IVI is a monorail system (not an over-the-wire system like ROTA), it may be similar to or consistent with the guidewire position.

3) A special ROTA wire (0.009 inch body and 0.014 inch tip) was replaced during ROTA operation which might affect guidewire bias by different support and compliance.

4) different positions between tip of the PCI guidewire and the ROTA wire, and the placement of the guide catheter may be changed, which may result in the inaccurate alignment between the ROTA burr movement route and the IVI catheter.

However, the condition of guidewire bias due to coronary anatomical characteristics (distortion and angulation, etc.) will not change. In most cases, IVI bias can reflect the uneven effect of ROTA, especially when the bias is in normal vascular segments, which easily lead to ROTA-related coronary dissections.

Our study showed that the quadrant of pre-ROTA OCT catheter bias was highly consistent (100%) with the location of ROTA-related dissections, which indicates position of the ROTA burr friction is closely associated with the position of the OCT catheter location highly.

However, wire bias could not be detected by angiography precisely unless IVI detection was performed, wire position appears to have been disturbed by the IVI catheter and the concept of wire bias may, upon further study be replaced by IVI catheter bias.

Another critical finding was that OCT catheter was always trapped beneath the intima (subintimal space) if ROTA-related dissection had occurred. This has potential clinical implications, as further replacement of a larger ROTA burr size may lead to further expansion and deepening of the dissection, and even perforation. So, the most important idea is to recognize ROTA-related dissection as early as possible and avoid further ROTA.[24] Coronary dissection caused by ROTA must be treated seriously and should be discontinued ROTA procedure once detected, otherwise more serious complications such as inhabited flow or coronary perforation may occur.[25] The sensitivity of angiographic ROTA-related coronary dissection was significantly lower than that of IVI detection, and even if the dissections were detected by angiography, it was not possible to determine whether the guidewire bias was beneath the dissections (subintimal space), so IVI-guided ROTA therapy was recommended to detect the ROTA-related dissection early and accurately.

Limitation

First, this was a retrospective observational study with a relatively small sample. Second, coronary dissection derived by ROTA is caused not only by wire bias, but also by manipulation. Third, OCT detection for whole lesion segment was less than 80% (16 cases) pre-ROTA in our study, which means nearly one in four patients. Even with OCT checking before ROTA, it is still not known whether guidewire bias is due to the heavy stenosis that the OCT catheter cannot pass through. Fourth, in this study, BTV did not draw the conclusion that it was related to the ROTA related dissection correlation, which may be due to the low overall BTV data in this study.

Conclusions

D_{cmb} and touch angle detected by OCT are two very valuable and convenient independent predictors of ROTA-related coronary intimal dissections caused by guidewire bias.

Declarations

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Figures

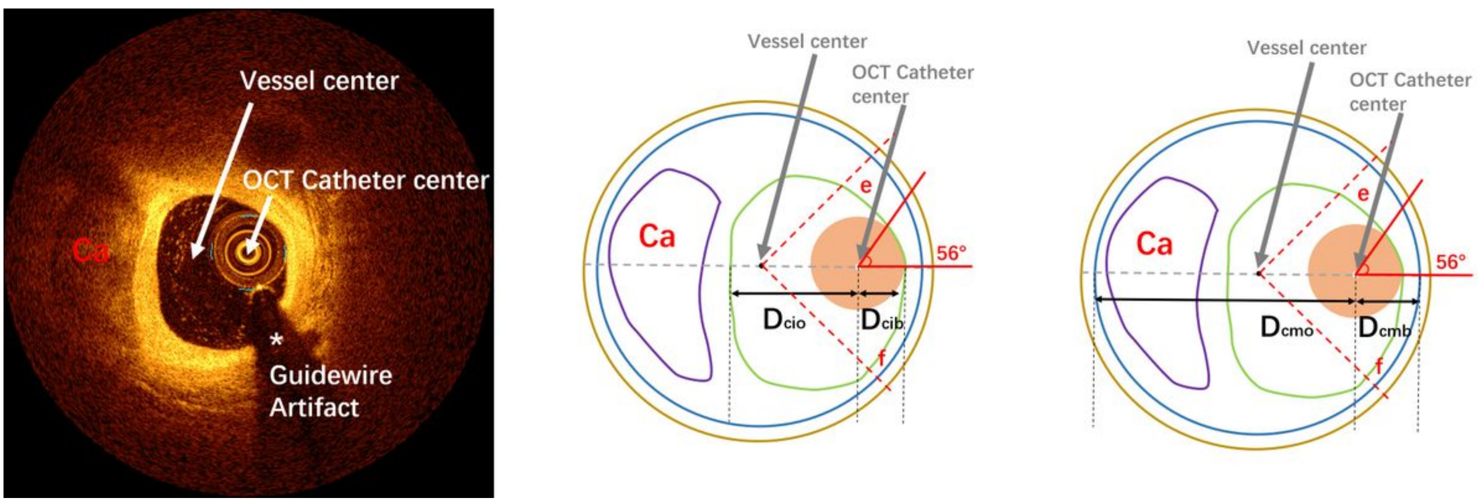

Figure 1

Pattern diagram of cross-sectional parameter measurement by OCT imaging: The left diagram represents OCT cross-sections image of calcified lesions, respectively. The upper middle and right images represent OCT measurements. In this diagram, the green line represents the intima, the blue line represents the media, the coffee line represents the extravascular, the purple line represents calcified plaques, and the fleshy circle represents the OCT catheter. Dcib: distance from center of IVI catheter to intima at the bias direction; Dcio: distance from center of IVI catheter to intima at the opposite side of the bias; Dcmb: distance from center of IVI catheter to media at the bias direction; Dcmo: distance from center of IVI catheter to media at the opposite side of the bias. The fan-shaped area between line e and line f (45º from the line between the center of the IVI catheter and the center of the vessel) is defined as the guidewire bias quadrant.

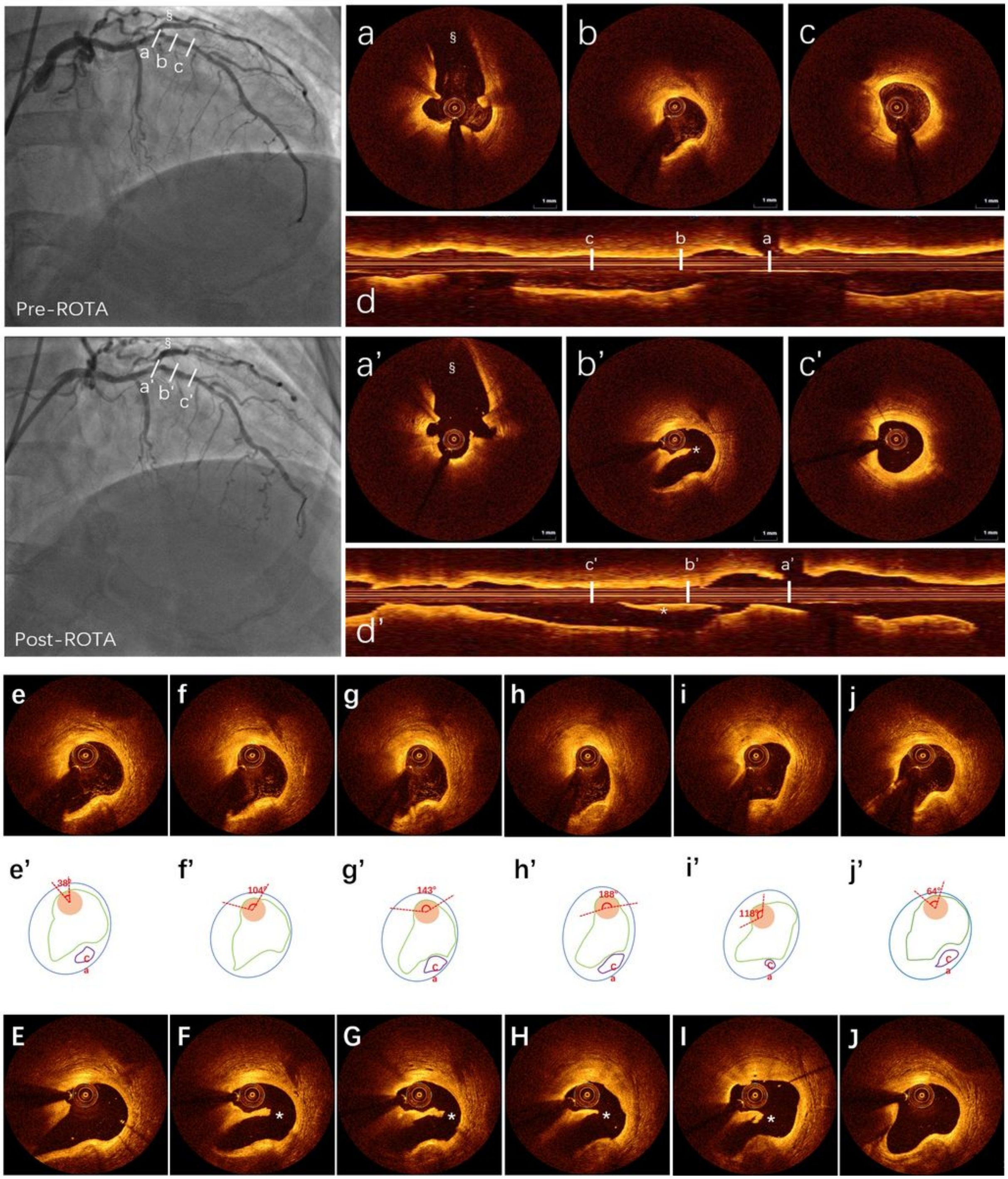

Figure 2

ROTA-related dissection measured by OCT post manual coregistration: First row: (a to c) three cross-sectional OCT images detection to identify wire bias pre-ROTA shown by angiography, in the top left, a: side branch ostium for manual coregistration; b: guidewire bias (OCT catheter bias to normal vessel wall); c: non-guidewire bias; d: longitudinal view of OCT pre-ROTA. Second row: (a' to c') same layers of cross-sectional OCT images post-ROTA after manual coregistration with same side branch in which angiography showed a haziness result in the below left, a': side branch; b': intimal dissection with OCT catheter trapped beneath the intima (subintimal space); c': without dissection; d: longitudinal view of OCT post-ROTA. *(b' and d') showed ROTA-related coronary dissection. §(angiography pre- and post-ROTA, a and a') showed side branch. OCT catheter bias to nearly normal vessel pre-ROTA (b) and intimal dissection occurred post-ROTA with OCT catheter trapped beneath the dissected intimal (b') in the guidewire bias quadrant. The third to fifth row: The third row shows the different catheter contact angles with vessel wall based on continuous OCT detection (e to j), the forth row of the schematic diagram shows the measurement method of the contact angle (e' to j'), and the third row shows the location of the procedure related coronary dissection after manual coregistration of OCT findings pre- and post-ROTA (E to J).