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2

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Running-title: Intraprocedural CT during CTO intervention

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ABSTRACT

Although intraprocedural coronary computed tomographic angiography (CCTA) allows for scanning during intervention without relocation of the patient, studies have yet to report on its use during chronic total occlusion (CTO) intervention. Therefore, we investigated the role of CCTA during CTO intervention, particularly whether CCTA could be used to evaluate the location of guidewires. A total of 61 patients scheduled for elective CTO intervention were consecutively enrolled and underwent CCTA and on-site analyses during intervention. Transverse axial and the curved multiplanar images in a 360-degree view were interactively used together to identify the location of guidewires, along with the adjustment of window condition. Intracoronary contrast-injection was used for specific cases requiring enhancement of the distal part of the CTO. Most CCTAs were performed to confirm the location of a single guidewire; CCTA was also performed to evaluate parallel (3 patients) or retrograde wires (5 patients). The initial identification rate for guidewire location was 56% with immediate transaxial images, but it significantly increased to 87% after interactive on-site uses of the curved multiplanar images (p <0.001). Cases in which guidewire location could be predicted with CCTA evaluation show a numerically higher success rate than those that could not (83% versus 63%), but not statistical significance (P=0.174). The mean time for CCTA evaluation and mean radiation dose were 8.6 minutes and 2.9 mSv, respectively. No specific complications occurred after CCTA and CTO procedures. Intraprocedural CCTA for identifying the location of the guidewires is feasible and safe when used for various CTO procedural steps.

Key Words: Computed Tomography; Coronary Occlusion; Coronary Intervention

Guidewire crossing is the key to successful chronic total occlusion (CTO) recanalization.¹⁻⁴ Use of intraprocedural imaging devices (e.g., intravascular ultrasound) is helpful but CTO lesions can be fully evaluated only after guidewire and imaging catheter crossing through the CTO.³⁻⁶ Moreover, the tip of a guidewire cannot be evaluated under side-mirroring systems equipped with current imaging devices. We built a coronary computed tomographic angiography (CCTA) system in the catheterization room (Yonsei University College of Medicine, Seoul, Korea) that allows for CCTA and coronary angiogram to be performed without taking patients off the table at any time during the intervention.⁷ Although preprocedural CCTA is helpful for CTO intervention, no data exist regarding the use of intraprocedural CCTA during CTO procedures.^{1,8,9} We investigated the role of intraprocedural CCTA during CTO intervention, with emphasis on whether CCTA could be used to evaluate the location and path of the CTO guidewires.

Methods

A prospective single-center design was used for this study. Between January and December 2014, patients scheduled for CTO intervention who had no specific contraindications for intraprocedural CT scanning were consecutively enrolled. CTO was defined as obstruction of a native coronary artery with thrombolysis in myocardial infarction flow grade 0 and an estimated duration \geq 3 months based on the clinical history or previous coronary angiography results.^{4, 6} All patients had typical chest pain or positive stress test results in various functional studies. According to Japan–Chronic Total Occlusion (J-CTO) score, CTO lesions were classified as easy (score=0), intermediate (score=1), difficult (score=2), and very difficult (score≥3).¹⁰ The institutional review board of the Yonsei University College of Medicine approved this study. Each enrolled patient received a detailed explanation of the study and provided written informed consent to participate.

We recently reported the first CTO case using the CCTA system.⁷ The CCTA system

comprises a 640 multi-slice CT scanner applying double-slice technology (Aquilion ONETM; Toshiba Medical Systems, Otawara, Japan) and a coronary angiography system, and allows for scanning to be performed during intervention without moving the patient on the table (Figure 1). The CT system has a wide detector width of 16cm, which allows for a full cardiac CT data set to be acquired within a single heartbeat. In the current study, CT scan was performed using a cranial-to-caudal acquisition with prospective electrocardiogram gating using the following parameters: collimation and slice thickness, 0.5 mm; reconstruction increment, 0.5 mm; tube rotation time, 0.275 seconds; tube voltage, 100 kV(p); current, dose modulation; and reconstruction field of view, 180 mm. The data were reconstructed at 75% of the R-R length. If motion artifacts were present, a different cardiac phase was selected. The following modulation was applied to the reconstruction: kernel, FC04; reconstruction algorithm, adaptive iterative dose reduction 3D. Sharp kernel with beam hardening collection was used to reduce metal artifacts. For intraprocedural CCTA scanning, the coronary angiogram system moved backward and the CT system moved forward for scanning (Figure 1). After scanning, the system operated in the reverse order and on-site analyses of the CCTA images were performed.

For specific cases that required enhancement of the distal part of the CTO, intracoronary contrast-injection was used during CCTA (Figure 2). The contrast medium (Visipaque 320 mg/mL; GE healthcare, Princeton, USA) was diluted with normal saline to obtain optimal coronary enhancement (300-400 HU). The concentration of diluted contrast medium is 12.61 mgI/mL to produce 400 HU of luminal attenuation under the 100 kVp. The diluted contrast medium was delivered with a dual-head power injector (Medrad Stellant Injector; Medrad, Indianola, PA) using the following protocols; injection rate of 5 mL/s and volume of contrast medium of 30 mL. The start buttons for the CT and the injector were pressed at the same time for CT scan. The CT scan started 2 seconds after the start button was

pressed. The CT scan time was 1.176 seconds, and injection was continuous for 6 seconds.

Before the CCTA, each patient's vital signs were evaluated, and a beta-adrenergic blocker (esmolol, 1 mg/kg) was administered intravenously if the heart rate was ≥ 65 beats/min and there were no contraindications to the use of beta-adrenergic blocking agents. The dose length product (DLP, mGy·cm) for CCTA was recorded. All radiation doses are presented as mSv, calculated as DLPx0.014. The mean times for scanning and moving of CCTA system, as well as time for CCTA analyses, including data transfer and the total radiation doses, were investigated.

Selected CCTA images were transferred to a workstation (Vitrea fx 6.4, Vital Images, Minnetonka, MN, USA), and then analysis for the identification of guidewire locations was performed. The double oblique and curved multiplanar reconstruction (C-MPR) images were obtained throughout the course of the coronary artery segments using a guidewire, and were used for the examination of guidewire location in a 360-degree view with the transverse axial images (Figure 3). Additionally, the window width and level was adjusted to distinguish between the guidewire and other structures.

By on-site review of these various results, we discriminated guidewires from the vessel structures, and investigated guidewire locations on longitudinal and cross-sectional sections. Based on the findings of CCTA, we predicted the possible locations of the guidewire-tip divided into three different zones (Figure 4): 1) intraplaque zone (suggestive of true lumen), case in which guidewires were located inside the vessel and clearly differentiated from vessel wall, 2) subintimal zone (suggestive of false lumen); cases in which the tip of the guidewire deviated to the lateral vessel wall and was not differentiated from the vessel wall; and 3) outside-vessel zone, cases in which the guidewire was completely out of the vessel wall.

Before coronary intervention, all patients received \geq 75 mg aspirin, and a loading

dose of 300 mg clopidogrel was administered at least 12 hours before the procedure. The choice of vascular access, CTO intervention techniques/devices, and use of intravascular ultrasound were left to the discretion of the operators. Successful CTO intervention was defined as a final thrombolysis in myocardial infarction flow grade of 3 and residual stenosis \leq 30% by visual assessment after stent implantation.

Continuous variables are expressed as a mean±standard deviation (SD) and categorical variables are presented as a number (%) and compared by chi-square test or Fisher's exact test. McNemar's test was used for comparisons of changes in incidences. Agreement regarding guidewire location was evaluated using Fleiss' kappa for multiple raters. In detail, four different observers including two interventionists and two specialized imaging cardiologists with level 3 clinical competence in cardiovascular CT imaging, assessed the location of guidewires.¹¹ P values <0.05 were considered statistically significant. Analyses were carried out using SPSS version 20 (IBM Corporation, Chicago, IL, USA) and R version 3.21 (R Development Core Team, Vienna, Austria).

Results

Between January 2014 and May 2015, a total of 61 patients who were scheduled for elective CTO intervention were consecutively enrolled and underwent CCTA and on-site analyses of CCTA images during intervention. The results for the patients' baseline characteristics and the procedures performed are presented in Table 1.

A summary of the CCTA evaluation and those results is presented in Table 2. Patients' vital signs were stable before and after CCTA evaluations. Intraprocedural CCTA was performed for various CTO types and procedures (Figure 5). In addition to showing the anterograde single wire, CCTA revealed the locations of retrograde and double wires used for parallel wire techniques.

The identification rate for guidewire location with was statistically significantly

improved after interactive on-site use of C-MPR images with adjustment of window condition (Table 2). Some axial images did not reveal the precise location of the guidewire tip, but the C-MPR images at different angles provided more accurate information about guidewire location (Figure 3). Inter- and intra-observer agreement values for guidewire location were almost perfect (κ =0.86 and 0.93, respectively).

After CCTA, various subsequent CTO procedures were performed (Figure 6). Comparing the success rates of CTO intervention according to the identification of guidewire location by CCTA, cases in which guidewire location could be predicted with CCTA evaluation show a higher success rate than those that could not (83% versus 63%), but not statistical significance (P=0.174) (Figure 6). No specific intraprocedural or in-hospital complications occurred after any of the CCTA and CTO interventions.

Discussion

To the best of our knowledge, this study was the first to investigate the implications of intraprocedural CCTA for CTO intervention. An important contribution of this study was the investigation of the role of CCTA in identifying the cross-sectional and longitudinal locations of guidewires during CTO procedures, without the use of invasive intravascular imaging tools. This study revealed that the use of intraprocedural CCTA for the identification of guidewire location and path during CTO intervention is feasible and safe and could contribute to the successful CTO intervention. Intracoronary catheter-based contrast-injection and combined assessment of axial and C-MPR images at different angles were also helpful for determination of guidewire location. However, not every intraprocedural CCTA result provided adequate information about guidewire location. Development of more strategies for improving image quality by reducing guidewire-related artifacts is needed.

The development of the intraprocedural CCTA system originally stemmed from the need for diagnostic and therapeutic workups for solid cancers and neurologic diseases and

rapid CT scanning during emergency room procedures.¹²⁻¹⁴ However, an intraprocedural CT system specific for coronary evaluation or intervention had not been developed or evaluated. As the clinical benefits of pre-procedural CCTA are well established and on-site evaluation could be important during the treatment of coronary artery diseases requiring immediate decisions for procedural success, the consecutive or shared use of both the angiography system and CT scanning could be tremendously useful in treating coronary artery diseases, especially for coronary interventions that treat complex lesions.¹⁵⁻¹⁷

We previously reported on the feasibility of a selective CCTA protocol in the catheterization room using low-dose contrast medium.¹⁸ Extending the application into therapeutic interventional fields, we also described a case in which the CCTA system was applied to CTO intervention.⁷ Herein, additional CTO cases were enrolled to clarify the role of intraprocedural CCTA. In the current study, intraprocedural CCTA evaluation to determine guidewire locations, especially at the guidewire-tip, was feasible and the guidewire location was fairly obvious. In the first application described in the previous case report, conventional cross-sectional CT images without contrast-injection were mostly used for the evaluation of guidewire location.⁷ However, in the current study, selective catheter-directed intracoronary contrast-injected CCTA was tested and clearer differentiation of the guidewire and vessel wall within the CTO segment was achieved by enhancing the segment behind CTO and the guidewire tip. C-MPR images at different angles were also used to examine the wire location. In prior studies evaluating the diagnostic accuracy of pre-procedural CCTA for detection of coronary stenosis, advanced image post-processing methods reportedly increased diagnostic accuracy.^{19,20} Similarly, the prediction rate of the guidewire location was significantly increased after interactive use of C-MPR images versus using the transverse images alone. In addition, although there was no statistically significant between the groups, cases in which the location of CTO guidewire could be predicted by CCTA evaluation tended to show a

higher success rate than those that could not, suggesting that CCTA could guide CTO intervention and contribute to the successful CTO intervention. Nevertheless, because there were cases in which CCTA did not reveal the location of the guidewire and was not as much help as we hoped, a better strategy for improving image quality is still needed.

Despite recent advances in techniques and technology for CTO intervention, CTO procedures may still require prolonged x-ray exposures and large volumes of contrast agent.^{1,4,21} In these situations, use of the intraprocedural CCTA system exacerbate these potential risks. Nevertheless, in the present study, acceptable radiation doses and minimal contrast volumes were used, and there were no associated complications after CCTA. The typical radiation doses used for conventional CCTA are 8-25 mSv, and second-generation CT scanners provide good image quality at low radiation doses (<3 mSv).²²⁻²⁴ The radiation dose used in this study was 2.9 mSv; a wide-detector scanner was used and the field of view could be reduced to a minimum, as the target view-point could be confined to the CTO lesion (including the guidewire), which was radiopaque on the scout film. Further advances in technology will enable further reduction in radiation doses. Use of contrast-injection was not required in one-half of the cases enrolled in this study. When contrast-injection was used, the diluted contrast was used and the actual contrast volumes required by the system was very minimal (mean volume, 1.1 mL). Selective intracoronary injection of the dilated contrast and the shorter scan time of the 640 multi-slice CT scanner applying double-slice technology allowed for use of smaller volumes.^{16, 25}

This study had limitations. First, the possible locations of guidewire were divided into three different zones based on the findings of CCTA. However, this classification could be arbitrary and the final decision regarding the location of guidewire could be subjective. The validating tests is needed to confirm the real location of guidewires. In addition, even though the inter- and intra-observer agreement results for guidewire location indicated perfect

agreement, no test exists to support this agreement. Second, because some CTO devices like re-entry devices were not available in Korea, the investigation regarding the roles of CCTA for these are lack. Third, although we reported acceptable radiation doses and contrast volumes of intraprocedural CCTA, further investigation regarding the cost and additional time for the application of this CCTA system are needed. Finally, we sought to evaluate the role of CCTA for the identification of guidewire location during CTO procedures. However, because CT scans have many other clinical uses, studies that investigate other potential roles of the intraprocedural CCTA system should be performed.

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Disclosure

Nothing to disclose.

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Figure Legends

Figure 1. CCTA system. CCTA system consisting of a CT scanner (a) moving forward and backward on a railroad system and a coronary angiography system (b) moving left and right (A). For an intraprocedural CCTA, the coronary angiogram system moves backward and then the CT scanner moves forward (B, C).

Figure 2. Comparison of CCTA images with or without intracoronary contrast-injection. When CCTA evaluation was performed without contrast injection (A to C), the determination of the vascular contour was difficult at the location crossing the guidewire-tip level (b to d in figure C). Using intracoronary contrast-injection (D to F), the distal portion of the guidewire tip was enhanced by contrast filling of collateral channels. The course of the artery was then clearly visible and the guidewire-tip location was more easily recognizable (b to d in figures F). Pre-procedural angiographic findings (A, D); angiogram indicating the guidewire location, before CCTA (B, E); C-MPR images (C, F) and the matched cross-sectional images (a to e). The red broken line and orange arrow indicate the wire-tip level and guidewire, respectively.

Figure 3. Prediction of guidewire location using C-MPR images. Pre-procedural angiographic findings (A, F) and angiogram indicating the location of the guidewire before intraprocedural CCTA evaluation (B, G). Transverse axial images did not reveal the guidewire location (C, H); however, the C-MPR images at the different angles clearly indicated the location of guidewire within the coronary artery (D and E, I and J). The red arrows and boxes indicate the wire-tip level and the corresponding axial images, respectively.

Figure 4. Classification of the location of the guidewires. The possible locations of guidewire were divided into three different zones based on the results of the transverse axial and C-

MPR images: 1) intraplaque zone (A); 2) subintimal zone (B); and 3) outside-vessel zone (C). C-MPR = curved multiplanar reconstruction.

Figure 5. Representative cases, various examples CTO intervention. Case no. 1, right coronary artery CTO (A). CCTA evaluation was performed during anterograde (B to D) and consecutive retrograde intervention (E to J). During the anterograde intervention (B), CCTA clearly revealed that guidewire was not within the coronary artery and definitely differentiated from the vessel wall containing calcification (C, D). After changing to retrograde intervention (E), CCTA revealed retrograde guidewire in the true lumen, contrary to the missed anterograde wire (F, G). Thus, the kissing-wire technique was attempted (H), and then the subsequent CCTA revealed anterograde wire in the true lumen, facing the calcification (I, J). Finally, stent implantation was successfully performed (K). Case no. 2, left circumflex CTO (A). The parallel wire technique was attempted (B). Two different wires are present on the cross-sectional images (C). CCTA revealed anterograde wire in the true lumen (D, E). Case no. 3, left anterior descending artery stent CTO (A). Anterograde wire nearly reached the distal true lumen, just crossing distal stent edge (B). CCTA was used to confirm the location of guidewire in the true lumen (C). The orange and blue arrows indicate the anterograde and retrograde guidewires, respectively. The asterisks indicate the locations of calcified plaques. Matching cross-sectional CCTA images (a to c) reveal the locations of the guidewires, and the red broken lines indicate the wire-tip level. CCTA = coronary computed tomographic angiography; CTO = chronic total occlusion.

Figure 6. Procedures and success rates according to the CCTA findings. CCTA = coronary computed tomographic angiography; CTO = chronic total occlusion.

Variable	(N=61)
Age (years)	61.5±10.5
Men	54 (89%)
Body mass index (kg/m ²)	25.7±3.2
Hypertension	43 (71%)
Diabetes mellitus	24 (39%)
Prior myocardial infarction	8 (13%)
Prior percutaneous coronary intervention	22 (36%)
Coronary bypass surgery	3 (5%)
Cerebrovascular accidents	4 (7%)
Ejection fraction (%)	57±13
Estimated glomerular filtration rate (ml/min/1.73 m ²)	80.0±15.1
Chronic total occlusion lesion characteristics	
CTO coronary artery	
Left anterior descending	26 (43%)
Left circumflex	7 (11%)
Right	28 (46%)
Stumpless occlusion	11 (18%)
Prior failed lesion	6 (10%)
Bridging collaterals	23 (38%)
Stent occlusion	5 (8%)
Pre-procedural computed tomographic evaluation	21 (34%)

Table 1. Baseline characteristics and procedures

Innon abronia total acclusion score	
Japan–emonie total occlusion score	
0	4 (6%)
1	12 (20%)
2	14 (23%)
≥ 3	31 (51%)
Chronic total occlusion procedures	
Approach	
Anterograde	47 (77%)
Retrograde	14 (23%)
Vascular accesses	>
Single femoral artery	12 (20%)
Both femoral arteries	38 (62%)
Femoral and radial arteries	11 (18%)
Contralateral angiogram	49 (80%)
Use of intravascular ultrasound	37 (61%)
Successful intervention	49 (80%)
Total number of stents (n)	1.9±0.7
Mean stent diameter (mm)	3.03±0.28
Total stented length (mm)	54.9±21.3
Total procedure time (min)	101.3±60.2
Total contrast volume used (mL)	361.3±112.6
Total radiation dose (mSV)	110.5±77.9

Quantitative angiographic analyses	
Reference vessel diameter (mm)	2.84±0.58
Chronic total occlusion length (mm)	22.6±10.9
Total lesion length (mm)	42.1±20.5
Post-procedural minimum lumen diameter (mm)	2.63±0.49

Data are presented as n (%) or mean ±SD.

Variable	61 patients
Systolic/ Diastolic blood pressure (mmHg)	137.7±20.2 / 67.8±10.1
Heart rate (beats per minute)	63.9±12.1
Total number of evaluation	72
Time for evaluation (minutes)	
Time for scanning and moving computed tomographic system	8.6±2.1
Time for coronary computed tomographic angiographic	8 5+1 0
analyses including data transfer	6.J±1.9
Total time, including test, system-moving, and analyses	17.2±2.9
Radiation dose (mSv)	2.9±1.5
Reasons for coronary computed tomographic angiography	
Penetration of proximal chronic total occlusion cap by	12 (190/)*
guidewire	15 (18%)*
Location of guidewire within chronic total occlusion segment	48 (67%)*
Entrance of guidewire into distal true lumen	11 (15%)*
Multiple coronary computed tomographic angiography during intervention	10 (16%)
Evaluation according to the change of the approaches or	
wiring techniques	4
Evaluation after guidewire progress	6
Use of contrast	
Non-contrast scanning	32 (52%)
Scanning with intracoronary contrast injection	29 (48%)

Table 2. Summary of coronary computed tomographic angiographic evaluation

Contralateral	27		
Ipsilateral	2		
Total diluted contrast volume used (mL)	28.5±9.7		
Actual contrast volume used (mL)	1.1±0.4		
Status of guidewire during coronary computed tomographic			
angiography			
Single wire	64 (89%)*		
Parallel wires	3 (4%)*		
Anterograde and retrograde wires	5 (7%)*		
Identification of the location of guidewire tip and path			
Initial identification only by transverse axial images	34 (56%)		
Final identification by multiple modalities	53 (87%)†		
Data are presented as number, number (%) or mean \pm SD.			

*Percentages from the total number of CCTA evaluation.

[†]p<0.001 by McNemar's test when compared to the incidence of initial identification of guidewire location.







Scanning without contrast



Scanning with contralateral intracoronary contrast injection





	A. Intraplaque zone	B. Subintimal zone	C. Outside-vessel zone
Transverse axial images	•		
C-MPR images			





#1. CCTA evaluation during retrograde intervention

#2. CCTA evaluation during parallel wire technique



#3. Stent CTO lesion



