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Novel proctorship effectively teaches interventionists coronary artery chronic total occlusion lesions☆,☆☆

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ABSTRACT

Background: Interventionists' experience and skills are essential factors for successful chronic total occlusion-percutaneous coronary intervention (CTO-PCI). However, the construction of theoretical strategy independent from interventionists' procedure may also improve it. We sought to assess the feasibility of CTO-PCI using an educational system supported by a single expert proctor.

Methods: A total of 160 patients underwent CTO-PCI between 2009 and 2016 at 92 Japanese centers in the Hands-on proctorship project. The CTO-PCI strategy was discussed with all participants and their specialists, before and during the procedure. We divided patients into 2 groups based on the CTO-PCI experience of their interventionist: (1) the less experienced group (CTO-PCI ≤50 cases, n = 65) and (2) the more experienced group (CTO-PCI >50 cases, n = 95). Baseline characteristics, procedural complications, and clinical outcomes were compared between groups.

Results: No significant differences in patient age, sex, prevalence for coronary risk factors, and lesion complexity was observed between groups. The retrograde approach was used equivalently between groups (55.4% vs. 60.0%, p = 0.56), and procedural success rates were similar (96.9% vs. 90.5%, p = 0.12). The rate of proctor's bailout for recanalization were not frequent between groups (4.6% vs. 5.3%, p = 0.85). No procedure-related mortality was noted in either group. In addition, no significant differences in procedural cardiac complications, including coronary dissection, perforation, or tamponade, were observed between groups (10.8% vs. 14.7%, p = 0.47).

Conclusions: The expert-supported CTO-PCI maintained high success rates regardless of interventionists' experience. This highlights the importance of theoretical strategy for the management patients undergoing CTO-PCI.

For decades, percutaneous coronary intervention (PCI) for patients with chronic total occlusion (CTO) has been considered one of the most technically challenging procedures, and it continues to have a certain degree of failure [1–3]. Although recent devices and technical developments enabled substantial improvements in the success rate of CTO lesions, interventionists' experience has been shown to be an important factor to maintain acceptable success rates [4–7]. Indeed, the overall success rate of CTO-PCI reported in the literature varies drastically, ranging from approximately 50% to 90% [1–10]. However, more recent data demonstrated that the introduction of the retrograde approach using a step-by-step hybrid algorithm significantly improved and stabilized the initial success rate of CTO-PCI to approximately 85–90% across multicenter registries from Japan, Europe, and the United States [7–10]. The procedure of CTO may be standardized in the current retrograde approach concept [11–12]. The development of theoretical strategy is also a necessary part of the success of CTO procedures, thus the optimal educational system should be required. A Japanese Hands-on proctorship project was initiated in December 2009 and focused on using education to raise awareness of the CTO procedure so that it would become a conventional, generalized practice. A clinical concern has now arisen with the CTO expert of the project to compensate or overcome interventionists' experiences in terms of safety and success rate of CTO-PCI. In this study, we sought to assess the feasibility of the

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Hands-on proctorship CTO-PCI project, as well as to compare procedural complications, clinical outcomes, and success rates of CTO-PCI based on interventionists' experience and skills.

1. Methods

A total of 160 patients underwent CTO-PCI across 92 centers in Japan between December 2009 and October 2016: 160 interventionists and 1374 physicians participated as part of the CTO Hands-on proctorship project. A CTO lesion is defined as total occlusion of the main branch that includes a second attempt of intervention. Coronary CTO was defined as a true total occlusion with complete interruption of antegrade blood flow as determined by coronary arteriography imaging (Thrombolysis in Myocardial Infarction [TIMI] flow grade 0). The tortuosity, calcification, lesion length, and lesion-specific characteristics of CTO lesions were defined according to a previously reported algorithm [13,14]. The total procedure time, amount of contrast medium, and radiation dose were also evaluated. Procedure time was defined as the total duration patients were in the catheterization room. Fluoroscopy time and radiation dose were recorded automatically by the cine device. Complications, including coronary perforation, dissection, thrombosis, and retrograde procedure complications such as donor vessel or collateral channel injury were also included. Procedural success was defined as residual stenosis <50% with TIMI flow grade 3 and without major adverse cardiovascular events [7]. Procedural characteristics, complications, and clinical outcomes, including death, were compared between two groups: (1) less experienced interventionists who conducted <50 CTO-PCI procedures before the Hands-on project, and (2) more experienced interventionists who conducted >50 CTO-PCI procedures before the Hands-on project. Clinical data from all patients with CTO lesions were prospectively recorded as part of the database of the CTO-PCI proctorship project. Data including patient status, clinical characteristics, laboratory data, presence of concomitant diseases, characteristics of CTO lesions, angiographic findings, revascularization procedure, and in-hospital mortality were collected. The medical ethics committee at individual centers approved this protocol, and written informed consent was obtained from all patients before undergoing CTO-PCI.

The Japanese Hands-on CTO-PCI proctorship project started at the beginning of December 2009. One expert of this field (Dr. Tsuchikane) had the sole responsibility of managing this project. All procedures were performed under the proctor's supervision. The project focused on pre-procedural planning and contemplating alternative bailout strategies. All experienced interventionists who intend to be a CTO expert in the future were allowed to join the project, either as a CTO interventionist, or as a member of the audience. Data concerning patient and lesion characteristics included angiogram or computed tomography (CT) could be shared with whole participants before the procedure if required. All participants discussed CTO-PCI strategy with an expert, including anatomy of CTO structure with angiogram and CT findings, the selection of guide catheter, first wire choice, and approach routes. The lecture included new device information and intravascular ultrasound (IVUS) findings were discussed depends on the situation. In regard to the bidirectional approach, the expert recommended that interventionists identify an optimal collateral channel, and prepared for the controlled antegrade and retrograde subintimal tracking (CART) technique. A step-by-step discussion of the CTO procedure was completed with all of the participants. One of the participants (not a first operator) presented a CTO strategy, thereafter the first operator presented his or her own strategy based on the preceding conference. The final strategy for CTO-PCI was decided on the proctor with meticulous discussion. There were no cases defined as ineligible for attempted PCI determined by the proctor after case presentation. During the procedure, the policy is to complete the procedure by the first operator alone. Depending on the situation, any positive advice, comments, and questions were welcomed to overcome the difficulties of the CTO procedure. As a last resort, the expert was consulted when the first operator had difficulties maintaining procedural success and safety. In this situation, the proctor performed the procedure instead of the first operator to cross the CTO lesions. Thus, the success rates of CTO in this study were divided as combined procedure success and first operator success. The rates of operator switching to the proctor during procedure were also compared between the 2 groups. After the procedure, a summary of the CTO case was discussed by the interventionist, all of the participants, and the CTO expert proctor.

All statistical analyses were performed using IBM SPSS statistics 22 (SPSS, Inc., Chicago, Illinois). Results are presented as mean ± standard deviation (SD). Categorical data were expressed as percentages of the total. Comparison between studied groups was made using a one-way analysis of variance for continuous variables and $\chi 2$ test. Statistical tests were all two-sided and p values <0.05 were considered statistically significant.

2. Results

Baseline patient characteristics and lesion variables are described in Table 1. Patients' average was 65.8 ± 9.8 years; they were predominantly men (92.5%). Patient age, sex, coronary risk factors, rate of hemodialysis, Canadian cardiovascular society III/IV, prior coronary artery bypass grafting, and old myocardial infarction were similar between groups (all p > 0.1). The overall rate of second attempted procedure for previous failed CTO lesions was 46.9%. This was similar between interventionists with less experience and those with more experience (53.8% vs. 42.1%, p = 0.14). The location of the target coronary artery in the main branch was not different between groups. In addition, no significant differences in tortuous, calcification, and length of CTO lesions were observed between groups (all p value >0.1). The rate of non-stump type CTO entry point was similar between groups (p = 0.34). As a result, average J-CTO score did not show any statistical significant difference between groups (1.8 ± 1.1 vs. 1.9 ± 1.2, p = 0.61).

Procedural characteristics are summarized in Table 2. Among 160 patients included in the study, less experienced interventionists performed 65 CTO-PCI procedures and more experienced interventionists performed 95. Interventionists with less experience were significantly younger than those with more experience (39.2 ± 4.0 years vs. 41.3 ± 3.7 years, respectively; p < 0.001). In addition, total interventional experience years, CTO experiences, and total PCI experiences were lower in the less experienced group than in the more experienced group (all p < 0.05). The primary antegrade approach was chosen in 71.9%. Of these, antegrade approach alone was performed in 33.1% and the rate of rescue bidirectional approach after antegrade failure was found to be 38.8%. In contrast, the primary retrograde approach was selected in 28.1% of total CTO procedures. The rate of approach route modification after the first operator presentation tended to be higher in well experienced operators than in less experienced operators (p = 0.064). Approach route and guide catheter chosen were predominantly the femoral artery (97.5%) and 8Fr size (78.1%). Approach route and guide catheter size were not different between groups (p = 0.25, and p = 0.43). Total procedural time and use of contrast media were similar between groups (240.2 ± 118.6 min vs. 243.0 ± 117.4 min; p = 0.88, 235.8 ± 102.5 ml vs. 223.4 ± 98.9 ml; p = 0.45). The retrograde approach was equally chosen between each group of interventionists (54.0% vs. 55.8%, p = 0.82).

The precise guidewire-crossing strategy in CTO lesions is indicated in Fig. 1. Antegrade wire cross was observed in 63 (42%) cases, whereas retrograde wire cross in 87 (58%). The antegrade wire crossing strategy was as follows: single wire cross (n = 42, 28%), parallel wire cross (n = 16, 11%), and IVUS guide wire cross (n = 5, 3%). The retrograde wire crossing strategy was as follows: reverse CART (n = 67, 45%), original CART (n = 3, 2%), kissing wire cross (n = 3, 2%), and retrograde wire cross (n = 14, 9%). Although a guide wire cross was used in one case, it failed to achieve a successful CTO-PCI with TIMI 0 final flow.

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Table 1
Baseline patient characteristics and lesion variables.

Variables	Overall n = 160	Less experience group n = 65	Well experience group n = 95	p value
Baseline clinical characteristics				
Age (years)	65.8 ± 9.8	66.0 ± 9.2	65.6 ± 10.2	0.76
Man	148 (92.5%)	60 (92.3%)	88 (92.6%)	0.94
Hypertension	119 (74.4%)	46 (70.8%)	73 (76.8%)	0.39
Diabetes	125 (78.1%)	52 (80.0%)	73 (76.8%)	0.64
Dyslipidemia	128 (80.0%)	56 (86.2%)	72 (75.8%)	0.11
Smoking	104 (65.0%)	39 (60.0%)	65 (68.4%)	0.27
Hemodialysis	6 (3.8%)	2 (3.1%)	4 (4.2%)	0.71
Canadian cardiovascular society III/IV	10 (6.3%)	5 (7.7%)	5 (5.3%)	0.53
Prior coronary artery bypass grafting	26 (16.3%)	12 (18.5%)	14 (14.7%)	0.53
Old myocardial infraction	72 (45.0%)	32 (49.2%)	40 (42.1%)	0.37
Lesion variables				
Second attempt	75 (46.9%)	35 (53.8%)	40 (42.1%)	0.14
Target coronary artery				
Left anterior descending	51 (31.9%)	23 (35.4%)	28 (29.5%)	0.73
Left circumflex branch	93 (58.1%)	36 (55.4%)	57 (60.0%)	
Right coronary artery	16 (10.0%)	6 (9.2%)	10 (10.5%)	
Lesion tortuous				
None	78 (48.8%)	33 (50.8%)	45 (47.4%)	0.90
Mild-moderate	70 (43.8%)	27 (41.5%)	43 (45.3%)	
Severe	12 (7.5%)	5 (7.7%)	7 (7.4%)	
Target lesion calcification				
None	53 (33.1%)	20 (30.8%)	33 (34.7%)	0.35
Mild-moderate	81 (50.6%)	37 (56.9%)	44 (46.3%)	
Severe	26 (16.3%)	8 (12.3%)	18 (18.9%)	
CTO lesion calcification				
None	63 (39.4%)	28 (43.1%)	35 (36.8%)	0.71
Mild-moderate	64 (40.0%)	25 (38.5%)	39 (41.1%)	
Severe	33 (20.6%)	12 (18.5%)	21 (22.1%)	
Occlusion length				
<20 mm	64 (40.0%)	30 (46.2%)	34 (35.8%)	0.19
≥20 mm	96 (60.0%)	35 (53.8%)	61 (64.2%)	
Morphology of entry point				
Stump type	86 (53.8%)	32 (49.2%)	54 (56.8%)	0.34
Non stump type	74 (46.3%)	33 (50.8%)	41 (43.2%)	
J-CTO score	1.9 ± 1.2	1.8 ± 1.1	1.9 ± 1.2	0.61
J-CTO score ≤ 1	68 (42.5%)	29 (42.6%)	39 (41.1%)	
J-CTO score = 2	43 (26.9%)	17 (26.2%)	26 (27.4%)	0.90
J-CTO score ≥ 3	49 (30.6%)	19 (29.2%)	30 (31.6%)	

Values are numbers (%) or mean ± SD. CTO, chronic total occlusion.

The overall success rate of CTO-PCI was 93.1% (149/160). The success rate of CTO-PCI is presented in Fig. 2, including overall and subdivided analysis of J-CTO score ≤1, =2, and ≥3. No significant differences were observed in the overall cohort between less and more experienced interventionists (96.9% [63/65] vs. 90.5% [86/95], p = 0.12), as well as J-CTO score ≤ 1 (96.6% [28/29] vs. 97.4% [38/39], p = 0.83), J-CTO score = 2 (100% [17/17] vs. 92.3% [24/26], p = 0.24), and J-CTO score ≥ 3 (94.7% [18/19] vs. 80.0% [24/30], p = 0.15). The rate the expert had to step-in to assist interventionists with recanalization was also similar between groups (4.6% vs. 5.3%, p = 0.85). No procedure-related in-hospital mortality was observed in either group. Combined cardiac complications, including coronary dissection, perforation, and collateral channel damage, were similar between groups (10.8% vs. 14.7%, p = 0.89). In addition, non-cardiac complications such as stroke, puncture site hematoma, and requirement of hemodialysis were similar between groups (all p > 0.1).

3. Discussion

Our results support the feasibility of the CTO Hands-on proctorship project. The pre-procedural discussion for theoretical strategy and technical advice during the procedure enabled an adequate success rate of CTO-PCI and acceptable complications, regardless of interventionists' background differences. Even less experienced interventional cardiologists will perform really well if they have expert cardiologists discussing the case before and looking over their shoulder during the procedure. The European CTO club states that at least 50 CTO PCI per year are mandatory to maintain the skill of procedure for interventional cardiologists [15]. However, there are no definitive criteria or minimum requirement to perform CTO-PCI for interventional cardiologists in Japan unlike in western countries. The total CTO-PCI experience of interventional cardiologists before this workshop was quite varied, ranging from 2 to 500 cases. Therefore, the current educational system may be effective to improve the success rates of CTO-PCI for less experienced trainees.

The procedural success rate of CTO-PCI was excellent in less and more experienced interventionists (96.9% vs. 90.5%, p = 0.12), even though the lesion complexity was similar between groups. The results remained constant even after subdividing J-CTO scores into ≤1, =2, and ≥3. Previous reports in non-Japanese countries reported that the primary retrograde approach was selected in 25% of the total CTO procedures; another report revealed that 41.4% of CTO procedures were performed using the retrograde approach as the primary approach and 54% were performed using the retrograde approach as the bailout approach after antegrade crossing failed [15–16]. These results did not contradict our findings. No procedure-associated deaths were observed, whereas the procedural complications were included in the minor collateral channel perforation or coronary perforation. Thus, the entire combined incidence of complications was relatively high. Especially, the rate of hemodynamic support was higher in less experienced operators than in more experienced operators. Efforts should be made to continue to decrease procedural complications during the procedure. Furthermore, the expert had to step-in to assist in the recanalization

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Table 2
Procedural characteristics and outcomes.

Variables	Overall n = 160	Less experience group n = 65	Well experience group n = 95	p value
Operator background				
Operator age	40.4 ± 3.9	39.2 ± 4.0	41.3 ± 3.7	0.001
Total years as interventionist	10.2 ± 4.1	8.9 ± 3.5	11.0 ± 4.3	0.001
Total CTO experience	84.0 ± 86.6	24.9 ± 11.1	124.5 ± 92.3	<0.001
Total PCI experience	908.8 ± 563.5	632.6 ± 332.3	1097.7 ± 610.9	<0.001
PCI experience of last year	114.4 ± 58.8	95.0 ± 37.6	127.3 ± 66.5	0.001
Periprocedural variables				
Success rates				
Combined procedural success	149 (93.1%)	63 (96.9%)	86 (90.5%)	0.12
First operator success	141 (88.1%)	60 (92.3%)	81 (85.2%)	0.85
Operator switched to the proctor	8 (5.0%)	3 (4.6%)	5 (5.3%)	
Primary antegrade approach	115 (71.9%)	51 (78.5%)	64 (67.4%)	0.13
Antegrade approach alone	53 (33.1%)	24 (36.9%)	29 (30.5%)	0.40
Bidirectional after antegrade fail	62 (38.8%)	27 (41.5%)	35 (36.8%)	0.55
Primary retrograde approach	45 (28.1%)	14 (21.5%)	31 (32.6%)	0.13
Proctor modified the first operator plan	19 (11.9%)	4 (6.2%)	15 (15.8%)	0.064
Puncture site				
Transfemoral approach	156 (97.5%)	65 (100.0%)	91 (95.8%)	0.25
Transradial approach	2 (1.3%)	0 (0.0%)	2 (2.1%)	
Transbrachial approach	2 (1.3%)	0 (0.0%)	2 (2.1%)	
Guide catheter size				
6 French	2 (1.3%)	0 (0.0%)	2 (2.1%)	0.43
7 French	33 (20.6%)	15 (23.1%)	18 (18.9%)	
8 French	125 (78.1%)	50 (76.9%)	75 (78.9%)	
Total procedure time (min)	241.9 ± 117.5	240.2 ± 118.6	243.0 ± 117.4	0.88
Contrast volume (ml)	228.4 ± 100.2	235.8 ± 102.5	223.4 ± 98.9	0.45
Fluoroscopy time (min), n	116.0 ± 70.3	111.2 ± 74.1	119.2 ± 67.9	0.49
Hemodynamic support system use	3 (1.9%)	3 (4.6%)	0 (0%)	0.035
Post-procedural variables				
In hospital death	0 (0.0%)	0 (0.0%)	0 (0.0%)	> 0.99
Combined cardiac complication	21 (13.1%)	7 (10.8%)	14 (14.7%)	0.89
Any coronary perforation	13 (8.1%)	3 (4.6%)	10 (10.5%)	0.18
Any coronary dissection	5 (3.1%)	2 (3.1%)	3 (3.2%)	0.98
Coronary thrombosis	2 (1.3%)	2 (3.1%)	0 (0.0%)	0.09
Cardiac tamponade	1 (0.6%)	0 (0.0%)	1 (1.1%)	0.41
Other non-cardiac complication				
Stroke	1 (0.6%)	1 (1.5%)	0 (0.0%)	0.23
Puncture site hematoma[a]	2 (1.3%)	1 (1.5%)	1 (1.1%)	0.79
Requirement of hemodialysis	0 (0.0%)	0 (0.0%)	0 (0.0%)	> 0.99

Values are numbers (%) or mean ± SD. CTO, chronic total occlusion; PCI, percutaneous coronary intervention.
[a] Requirement of transfusion >2 unit.

of CTO lesions at a similar rate between groups (4.6% vs. 5.3%, p = 0.45). These results suggest that the initial success rate for CTO-PCI among all the interventionists who participated in the project are possibly gained beyond 85% without intentional procedure support by an expert. The success rates we observed were comparable to those reported in the literature [1–10]. This is supported by the effectiveness of this workshop project. However, the definition of CTO success was different due to each registry's criteria. Procedural success was defined as residual

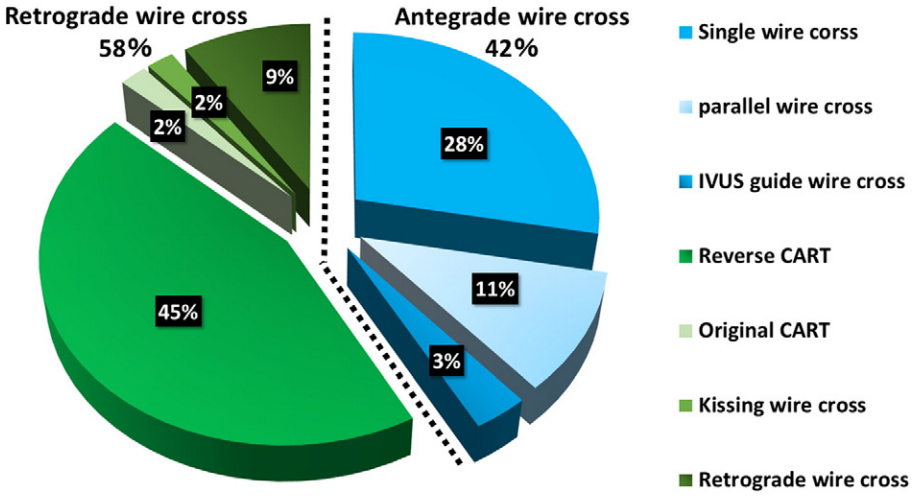

Fig. 1. The precise guidewire-crossing strategy in CTO lesions.

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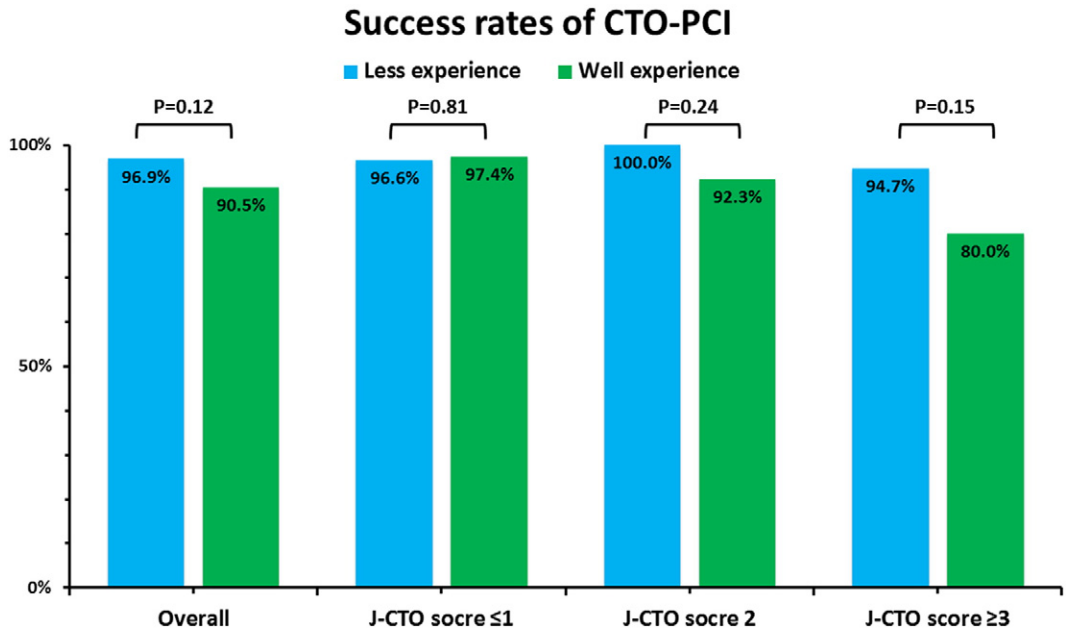

Fig. 2. The success rate of CTO-PCI in the overall and subdivided analysis of J-CTO score ≤1, =2, and ≥3 groups.

stenosis of <20–30% in the other CTO registry data (15–16), whereas the current data were applied to the definition of CTO success as diameter stenosis <50% [7]. These differences may affect the high procedural success rates of this study although the wire and conventional balloon completely crossed the CTO lesions in cases defined as successful CTO. The key factors for initial CTO-PCI success were originally believed to be based on interventionists' experience and skills [4–6]. In addition, it has been previously reported that the success rate of CTO-PCI ranged widely from 50% to 90%, suggesting the importance of physician dependence [1–10]. However, the Hands-on project evaluated here achieved similar outcomes, compared with those from the most recent results reported by multicenter CTO expert registries across the globe [7–10]. Currently, we believe that CTO interventionists should understand the right way to manage patients with CTO beyond handling the guide wire itself. Our results indicate that CTO interventionists should also carefully understand and plan ahead, and have a step-by-step discussion before and during the procedure.

Due to procedural difficulties, some patients with CTO lesions were left without revascularization unless they had clinical symptoms or coronary ischemia. Several previously published studies have demonstrated that patient prognosis was significantly improved if they had successful CTO-PCI, compared with those who had a failed CTO-PCI [17–18]. The complete revascularization of patients with multi-vessel disease has also been associated with a reduced risk of mortality and major adverse cardiac events [19–20]. Residual CTO lesion was a negative factor to perform the complete revascularization. Although the beneficial effects of CTO treatment are challenging to evaluate objectively, recanalization of CTO lesions should be accomplished completely, even if any experience interventionist is challenging.

The best method to learn CTO remains uncertain for less experienced interventionists. In general, interventionists learn topics such as guide catheter, guide wire concepts, evaluation of intravenous ultrasound, and retrograde concept from textbooks or clinical reports [21–22]. Live demonstrations are also considered effective educational tools to learn CTO procedures [23]. Many cardiologists and physicians can share these updates in live case demonstrations of CTO-PCI at cardiology congresses. In one study, a proctorship-supported procedure also improved CTO success results, although the success rate was only 77.5% [24]. In addition, other educational programs similar to the Hands-on project, have contributed to better outcomes among patients undergoing CTO-PCI. Further follow-up programs should be required to improve CTO-PCI results and to share them with global interventional cardiologists.

We acknowledge several limitations in our study. This educational Hands-on proctorship project was managed by a single expert CTO interventionist during a 17-year-effort. Therefore, it is unclear whether this educational system can be generalized to other educational courses or expert CTO proctors. This was a cross sectional study focused on the acute results of the proctorship for complex CTO lesions. In addition, many operators with different experiences joined this workshop. Unfortunately, we do not have enough data to demonstrate the durability and outcomes in the years. We believe that this project is a useful educational tool and a first step toward future improvements of CTO-PCI patient outcomes for the next generation CTO interventionists. There rate the expert had to step-in to assist first operators with recanalization of CTO lesions was low. However, it was noted >85% of success rates of CTO-PCI were confirmed regardless of the interventionist's experience when taking into account the rate the expert had to step in. Patient selection for CTO-PCI cases depended on the individual centers, but we observed that the lesion complexity did not different between groups. This proctorship project provide a method of education that still respects the experience of proctor and independently considers the strategy and procedure of CTO-PCI. That may lead to relatively lower success rates of CTO-PCI in more experienced interventionists. Therefore, some selection and situation bias were inevitable.

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