Influence of a long-term proctoring process on the effectiveness of chronic total occlusion percutaneous coronary interventions

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ABSTRACT

Background: Despite the complexity of the chronic total occlusion (CTO) percutaneous coronary intervention (PCI) procedures and unsatisfactory results in centers with low volume experience, the practice of training and certifying operators is not a routine.

Aims: The study aimed to identify factors influencing the effectiveness and complications of PCI CTOs during a proctoring program.

Methods: The study group consisted of 194 consecutive patients (226 PCI CTOs) as part of the proctoring program. The relationships between clinical and treatment parameters and the experience gained along with the duration of the proctoring program on the effectiveness and safety of the procedure were assessed.

Results: The multivariable analysis showed an independent effect of CTO morphology (odds ratio [OR], 0.38; 95% confidence interval [CI], 0.21–0.71; P <0.01) and an independent effect of increasing operator's experience (OR, 2.62; 95% CI, 1.24–5.60; P = 0.01) on the effectiveness of the procedure. The increase in the efficiency of the PCI CTO, related to the treatment experience gained during the program, was observed especially in the first 50 procedures, treatment effectiveness increased from 55% to 72% (P <0.05). The success of procedures was higher in months when ≥3 procedures were performed (75% vs. 52%; P <0.001). Periprocedural complications occurred in 11 patients (4.9%). In the multivariable analysis, no independent factors influencing the risk of complications were identified.

Conclusions: The effectiveness of PCI CTO depended on lesion complexity and broadening operator's experience. No independent factors affecting the risk of complications were identified. The number of >50 procedures under the proctor's supervision should be considered in designing teaching programs.

Key words: chronic total occlusion, experience, percutaneous coronary intervention, proctoring, success

INTRODUCTION

The chronic total occlusion (CTO) percutaneous coronary intervention (PCI) is the most complex percutaneous coronary procedure [1, 2]. PCI CTO requires skills of a highly specialized operator and has high costs resulting from the need to use expensive, technologically advanced equipment. Technical complexity determines the higher complication rate (1.6% vs. 0.8%) and lower efficiency of PCI CTO (70% vs. 97%) compared to routine PCI [2–5]. As a result of the technological advancement made in recent years, these differences gradually disappear in the clinical

WHAT'S NEW?

In our study, we investigated whether lesion complexity and operator's experience gained during educational program under the proctor's supervision were independent factors influencing the success of percutaneous coronary intervention for chronic total occlusion (PCI CTO) determined in multivariable analysis. The supervision of a proctor significantly increased the effectiveness of training in a low-experienced center compared to the self-acquired experience presented in other studies. The increase in effectiveness was greatest during the first 50 procedures of the proctoring process, which may be a factor to consider in designing training programs. The success of PCI CTO procedures was higher in months when ≥3 procedures were performed. Any independent factors affecting the risk of complications were not identified.

centers with the highest level experience, nonetheless, they remain in the centers with limited experience (91% vs. 54%) [1–3, 6–10].

Significant differences between centers concerning the effectiveness of treatments do not constitute a formal premise for the introduction of PCI CTO accreditation. The process of implementation of the PCI CTO procedure along with educating the operators is not standardized and not subject to routine evaluation. This remains in contradiction with the invasive cardiology practice in introducing complex interventions. For example, the left atrial appendage occluder implantation or the percutaneous implantation of aortic valve prostheses are not recommended in non-accredited centers [11, 12]. The process of training operators remains under strict supervision. It covers the theory, exercises on simulators, and a clinical phase under the proctor's supervision. Granting approval by the Food and Drug Association for the therapeutic use of new devices in the United States depends, among others, on the documentation of the training process effectiveness. Each of the training phases is assessed, and its completion is mandatory to obtain the operator's certificate. Otherwise, it is not possible to purchase equipment for procedures from the manufacturer [13–15].

Despite the complexity of PCI CTOs and unsatisfactory outcomes in centers with little experience, the practice of certifying centers and operators is not routine. The "CTO Club" indicates in their recommendations the key importance of the educational process [1, 2]. Among educational models, the practical hands-on training conducted with an experienced operator (proctor) is characterized by the highest efficiency. Initial experience shows that the effectiveness of the procedure obtained during the training is significantly higher and achieved much faster than in the case of independent education [16–18]. So far, the duration of such designed programs has not been determined. Therefore, this study aimed to assess the impact of the duration and other potential factors related to the proctor's training program on the effectiveness and complications of the PCI CTO.

METHODS

Study group

The study group consisted of consecutive patients who underwent PCI CTO in 2012–2017 at the Military Institute of Medicine in Warsaw as part of a proctored training program. A CTOs were defined as a total obstruction of the artery of at least 3 months duration with preserved but impaired native flow through the microchannels or bridging blood flow, and complete occlusion with retrograde filling of the peripheral artery from the collateral circulation. Data relating to the characteristics of the study group and endpoints were obtained from medical records, procedure descriptions, and angiographic films. The morphological characteristics of the occlusion were determined using the Japanese Chronic Total Occlusion (J-CTO) score. The J-CTO scale is a five-point scale consisting of entry shape, calcifications, bending >45%, occlusion length, and re-try lesion (one point for each) [19, 20]. Inclusion criteria were angina symptoms caused by exercise or ≥10% induction of ischemia in the vascular area of the occluded coronary artery confirmed by imaging examinations. The exclusion criteria were the patient's refusal, uncorrected anemia, hemodynamic instability, respiratory failure, or other causes that prevented the patient from undergoing a potentially long endovascular procedure.

Design of the proctoring program

Four interventional cardiologists employed at the Department of Cardiology with ≥15 years of procedural experience in percutaneous coronary interventions but with a limited experience in the PCI CTO participated in the proctor's training program. The process of qualifying patients, planning the treatment strategy, the educational process of the operators, and the team participating in the procedures, were managed by the proctor who is a well-known and respected operator in the field of CTO PCI and the head of one of the leading in this field cardiology centers in Europe.

The assumptions of the proctoring program included the proctor's supervision over each of the procedures. The proctor supervised all stages of the treatment, from patient qualification to the procedure, through comprehensive angiographic evaluation, and the selection of the appropriate treatment technique in all cases. The treatment strategy implemented during the program assumed the routine usage of the "antegrade wire escalation, antegrade dissection, re-entry" technique, and in the event of failure, the "retrograde, CART (controlled antegrade and retrograde subintimal tracking) and reverse CART" technique using guidewires and microcatheters tailored to perform PCI CTO. Contralateral injections were routinely used. We used quintiles of the number of treatments for subsequent periods assessing the effectiveness and complications of the procedure during the training program.

Informed consent was obtained from each patient. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee (Bioethics Committee of the Military Institute of Medicine No. 56/WIM/2017).

Aim of the study

The endpoint of the study was the success of the procedure, defined as the artery recanalization accompanied by a flow to the peripheral section (TIMI 3), completed with stent implantation.

The complex endpoint assessing the safety of the procedures included the occurrence of acute periprocedural complications. Death, resuscitated sudden cardiac arrest, myocardial infarction (MI), aortic dissection, tamponade, significant bleeding, and stroke were taken into consideration.

Statistical analysis

The study protocol assumed the separation, in the multivariable analysis, of clinical and periprocedural parameters and operators' experience gained as a result of the implementation of the program, independent factors affecting the endpoint of the study, and a complex endpoint assessing the safety of the procedures.

Continuous variables are presented as mean with standard deviation (SD) or median with interquartile range (IQR) and compared between the groups using Student's t-test or the Wilcoxon rank-sum test, respectively. Categorical variables were reported as frequency in a given group by number and percentage, and differences in frequencies were compared between successful and unsuccessful procedures using Fisher's exact test (for binary variables) or the χ^2 independence test (for variables having more than two levels, we used a simulated *P*-value). To identify independent factors predicting the effectiveness and complications of the procedure, the logistic regression model was used. The reported estimation results present models estimated including all variables that were hypothesized to be clinically significant (patient age, chronic kidney disease, previous coronary artery bypass grafting [CABG], previous PCI, ejection fraction [EF] <35%, J-CTO and the impact of the experience) — a single model was estimated, no statistical selection of variables was performed to avoid bias in the estimates of the reported p-values that could be introduced by model selection procedures. The statistical significance of parameters was used to analyze the estimation results, assuming the significance level of 0.05. Statistical analysis was performed with R 4.1.0 and Julia 1.6.2 software and their compliance was verified.

RESULTS

Clinical characteristics

The study group consisted of 194 patients aged mean (SD) 65 (10) years (75% men). More than half of the patients have had a previous myocardial infarction (50%) or angioplasty (PCI) (57%) and 13% had a history of CABG. The mean (SD) value of the EF was 51% (9%). The low ejection fraction (<35%) patients constituted 2.7% of the study group. Patients with diabetes mellitus constituted 42% and patients with chronic kidney disease 21% of the study group. A total of 226 coronary arteries underwent the procedure; 156 (69%) were effectively recanalized. The proctor performed the procedure in 81 out of 226 cases (35.8%) throughout the whole educational program. Four operators participating in the program were engaged in all performed procedures, either actively (in 145 procedures) or passively as assistants and observers. The distribution of the main risk factors did not differ between the groups of patients with successful and unsuccessful revascularization (Table 1).

Treatment characteristics

The CTO recanalization procedure was most often performed in the right coronary artery (RCA) (n = 128; 57%). The percentage of complex procedures (J-CTO ≥2) was 37%. Out of all 226 procedures performed, the "antegrade" technique was used in 205 (90%), including the wire escalation technique in 156 cases (67%) (Table 1). The median (IQR) radiation dose was 2286 (1340–3496) mGy, the median (IQR) volume of contrast administered was 280 (200–400) ml. The morphological complexity of the occlusion (J-CTO ≥2), the presence of calcifications, and the occlusion angle >45° occurred statistically significantly more often in the group of ineffective procedures. The effectiveness of the procedure in the J-CTO <2 group was significantly higher than in the J-CTO ≥2 group (71% vs. 30%; *P* <0.01).

The endpoint of the study — the impact of clinical, angiographic, and periprocedural parameters, as well as growth in operators' experience, on the effectiveness of CTO recanalization procedures

An independent, statistically significant effect on success of the procedure was demonstrated for morphological com-

Table 1. Clinical and procedural characteristics in relation to the effectiveness of the procedure

Variable	All procedures	Successful procedure	Unsuccessful procedure	*P*-value
Number of procedures, n (%)	226 (100)	156 (100)	70 (100)	<0.01
Age, years, mean (SD)	65.29 (9.9)	64.93 (9.78)	66.09 (10.29)	0.43
Male gender, n (%)	169 (74.78)	114 (73.08)	55 (78.57)	0.48
Hypertension, n (%)	187 (82.74)	127 (81.41)	60 (85.71)	0.55
Diabetes mellitus, n (%)	95 (42)	65 (41.67)	30 (42.86)	0.14
Smoking, n (%)	78 (34.51)	53 (33.97)	25 (35.71)	0.92
Dyslipidemia, n (%)	138 (61.06)	91 (58.33)	47 (67.14)	0.27
CKD, n (%)	48 (21.23)	36 (23.08)	12 (17.14)	0.41
Hemodialysis, n (%)	6 (3.09)	5 (3.21)	1 (1.42)	0.18
Previous MI, n (%)	114 (50.44)	73 (46.79)	41 (58.57)	0.14
Previous PCI, n (%)	128 (56.64)	86 (55.13)	42 (60)	0.59
Previous CABG, n (%)	30 (13.27)	19 (12.18)	11 (15.71)	0.61
Previous stroke, n (%)	16 (7.08)	11 (7.05)	5 (7.14)	1.00
EF, %, mean (SD)	51.39 (8.99)	51.53 (9.19)	51.1 (8.55)	0.2
CCS, n (%)				
0	2 (0.88)	0 (0)	2 (2.86)	0.11
1	63 (27.88)	44 (28.21)	19 (27.14)	
2	95 (42.04)	66 (39.10)	29 (41.43)	
3	36 (15.93)	27 (17.31)	9 (12.86)	
4	1 (0.44)	0 (0)	1 (1.43)	
CTO target vessel				
Right coronary artery, n (%)	128 (56.6)	80 (51.28)	48 (68.57)	0.1
Left anterior descending artery, n (%)	34 (15.04)	24 (15.38)	10 (14.29)	
Left circumflex artery, n (%)	62 (27.43)	50 (32.05)	12 (17.14)	
Intermediate branch, n (%)	1 (0.44)	1 (0.64)	0 (0)	
Venous graft, n (%)	1 (0.44)	1 (0.64)	0 (0)	
Procedural technique				
Antegrade, n (%)	205 (90.7)	152 (97.44)	53 (75.71)	<0.01
Wire escalation, n (%)	151 (66.8)			
Dual injection, n (%)	78 (34.5)			
Retrograde, n (%)	21 (9.3)	4 (2.56)	17 (24.29)	
Anatomical factors				
J-CTO, n (%)				
0	75 (33.2)	56 (35.9)	19 (27.14)	<0.01
1	68 (30.09)	54 (34.62)	14 (20)	
2	40 (17.7)	25 (16.03)	15 (21.43)	
3	25 (11.06)	15 (9.62)	10 (14.29)	
4	13 (5.75)	4 (2.56)	9 (12.86)	
5	5 (2.21)	2 (1.28)	3 (4.29)	
J-CTO ≥2, n (%)	83 (36.73)	46 (29.49)	37 (52.86)	<0.01
J-CTO <2, n (%)	143 (63.27)	110 (70.51)	33 (47.14)	
Occlusion length, n (%)	94 (41.59)	59 (37.82)	35 (50)	0.11
Blunt stump/entry, n (%)	53 (23.45)	33 (21.15)	20 (28.57)	0.24
Calcifications, n (%)	73 (32.3)	43 (27.56)	30 (42.86)	0.03
Bending >45°, n (%)	58 (25.66)	26 (16.67)	32 (45.71)	<0.001
Exposure factors				
Radiation dose, mGy, median (IQR)	2286 (1340–3496)	2183 (1253–3287)	2869 (1628–4090)	0.04
Radiation dose, mGy, in J-CTO <2, median (IQR)	1877 (981.5–3134.5)	1957 (1013–3185)	1678 (931–3064)	0.72
Radiation dose, mGy, in J-CTO ≥2, median (IQR)	3047 (1895–4328)	2482 (1880–3880)	3404 (2263–4697)	0.03
Contrast volume, ml, median (IQR)	280 (200–400)	300 (200–400)	250 (165–400)	0.56
Contrast volume, ml, in J-CTO <2, median (IQR)	225 (160–350)	230 (150–350)	200 (160–300)	0.4
Contrast volume, ml, in J-CTO ≥2, median (IQR)	350 (225–500)	354.5 (280–457.5)	350 (200–500)	0.28

Abbreviations: CABG, coronary artery by-pass graft; CCS, Canadian Cardiovascular Society; CKD, Chronic kidney disease; CTO, chronic total occlusion; IQR, interquartile range; J-CTO, Japanese Chronic Total Occlusion score; EF, ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation

Table 2. Multivariable analysis of the influence of selected variables on the effectiveness of the treatment

	OR (95% CI)	*P*-value
Age	0.98 (0.94–1.01)	0.16
CKD	1.75 (0.78–4.16)	0.19
Previous CABG	0.88 (0.37–2.17)	0.78
EF <35%	1.01 (0.97–1.04)	0.74
J-CTO ≥2	0.38 (0.21–0.71)	0.002
Previous PCI	0.69 (0.37–1.29)	0.25
Operator experience	2.62 (1.24–5.60)	0.012

Abbreviations: CI, confidence interval; OR, odds ratio; other — see Table 1

Table 3. Multivariable analysis of the influence of selected variables on the occurrence of complications

	OR (95% CI)	*P*-value
Age	1.02 (0.98–1.06)	0.32
CKD	1.09(0.43–2.64)	0.84
Previous CABG	0.52 (0.12–1.63)	0.32
EF <35%	1.00 (0.96–1.04)	0.92
J-CTO ≥2	0.83 (0.38–1.77)	0.64
Previous PCI	0.97 (0.47–2.02)	0.93
Operator experience	0.99 (0.41–2.68)	0.99

Abbreviations: see Table 1 and Table 2

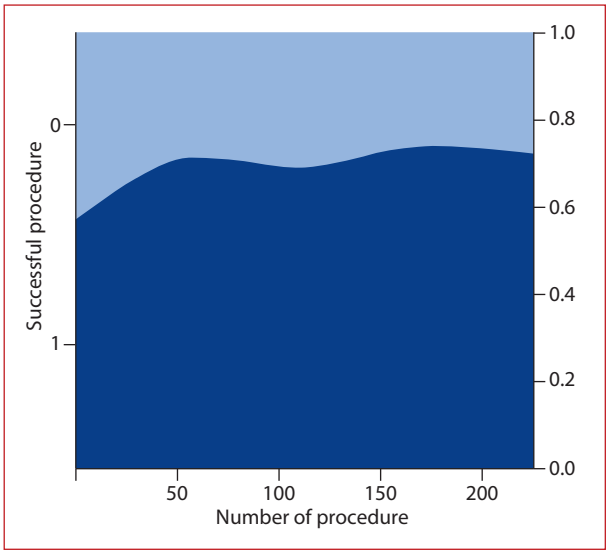

Figure 1. Plot of the conditional probability of successful procedure as a function of the number of procedures

plexity of the lesion (J-CTO≥2) (odds ratio [OR], 0.38; 95% confidence interval [CI], 0.21–0.71; *P* <0.01) and operator's experience (OR, 2.62; 95% CI, 1.24–5.60; *P* = 0.01) (Table 2). A higher J-CTO score resulted in decreased success of CTO PCI, and experience gained during the proctoring program increased the effectiveness of the procedure. The remaining variables did not affect the success. The increase in the efficiency of CTO recanalization, related to the acquired procedural experience, was observed especially during the first 50 procedures (Figure 1). The treatment effectiveness increased between the first and the remaining quintiles of the program from 55% to 72% (*P* <0.05). In the months with more than 3 PCI CTOs performed, a higher percentage of successful recanalization was achieved compared to the months with less than 3 procedures (75% vs. 52%; *P* <0.001).

A composite endpoint assessing safety

Periprocedural complications occurred in the case of 11 patients (4.9%). One patient died, 3 patients experienced myocardial infarctions, 3 patients had tamponade, one patient had aortic dissections, and 3 patients were successfully resuscitated from sudden cardiac arrest. No patients experienced significant bleeding or stroke. No independent factors affecting the risk of complications were identified in the multivariable analysis (Table 3). The absorbed median (IQR) radiation dose was significantly higher in complex occlusions (J-CTO <2 vs. J-CTO ≥2: 3047 (1895–4328) mGy vs. 1877 (981.5–3134.5) mGy; *P* <0.01). The median (IQR) volume of the administered contrast also was significantly higher in the case of complex procedures (350 [225–500] ml vs. 225 [160–350] ml; *P* <0.01).

In this study, the influence of the volume of contrast and radiation dose on the occurrence of complications was not assessed.

DISCUSSION

The complexity of CTO procedures and their complications require using proven educational programs and professional supervision at the implementation stage [1]. The recommendations of the "CTO Club" lead operators to "online" didactic programs that enable learning. These online programs start from the correct interpretation of angiographic images in the context of the use of appropriate treatment techniques, discuss differences regarding the technical properties of the angioplasty equipment and the principles of its selection depending on the angiographic image and the course of the procedure [2].

The measurable effect of the experience gained is the increase in operator effectiveness. For example, in a meta-analysis of 65 studies published in 2013, Patel et al. [21] showed an 11-year upward trend in the effectiveness of CTO recanalization from 68% to 79%. The similar dependence between the effectiveness and the number of recanalizations performed was documented in a seven-year registry of 94 000 procedures; their effectiveness in groups of operators performing 1–10, 11–50, >50 treatments per year was 58.4%, 65.6%, and 72.7%, respectively [18].

Theoretical knowledge of PCI CTO is not sufficient to obtain satisfactory treatment results even among experienced operators who do not have practical experience in CTO recanalization. An expert opinion of the Association of Cardiovascular Interventions of the Polish Cardiac Society emphasizes the role of experience in obtaining high efficiency of CTO PCI procedures, indicating the number of 50 procedures per year as the minimum that allows achieving sufficient effectiveness [22]. Due to the

awareness of this fact, it was necessary to base the practical education process on direct consultations and substantive supervision at the operating table by operators-teachers experienced in performing such procedures. In 2017, Yamamoto et al. [16] published data on the impact of proctoring on the effects of CTO recanalization procedures in 2009–2016, demonstrating comparable effectiveness of recanalization among experienced and inexperienced operators after the completion of the proctor's program (96.9% vs. 90.5%; $P = 0.12$) [16]. The impact of the proctoring process on the increase in the effectiveness of PCI CTO was also documented by Sharma et al. [17] who reported on the effects of 232 procedures performed before proctoring and 355 procedures performed after the implementation of the proctoring program, showing an increase in the percentage of effective recanalizations from 62.1 to 77.5% ($P < 0.001$). In particular, the effectiveness of procedures that were technically difficult due to the complex morphology of the occlusion increased (J-CTO ≥2 from 49.5% to 70.7%; $P < 0.001$) [17].

PCI CTO proctoring programs find many enthusiasts. However, the framework of such programs, their form and duration, have not yet been defined. In this context, the results of the presented study provide new information. Over the course of the 6-year program, an effective increase in the efficiency of recanalization from 56% to 73% was documented in the first 18 months of the program. After the first 50 procedures, the impact of the proctoring process was not noticeable, and the effectiveness of the procedures remained unchanged for the next 4.5 years of the study. However, there is a noticeable dynamic increase in efficiency, which allowed for higher efficiency than in the already-discussed seven-year registry of 94 000 non-proctored procedures performed by inexperienced operators, where after 7 years the effectiveness of recanalization was 61.4% [18]. The results of the analysis by Brilakis et al. [3] from 2015, which documented the dynamics of the increase in the effectiveness of CTO recanalization procedures in the non-proctored program, indicated the decisive role of the first 20 procedures, at the same time flagging the importance of the number of procedures performed by operators (<5 = 53.1%, 5–1 = 62.1%, and >10 = 74.6%; $P < 0.001$). The results of the research of Brilakis et al. [3] correspond with the results obtained in our study. The lowest efficiency of recanalizations was recorded in the months when the number of procedures performed fell below three.

As far as we know, the results obtained in our study show for the first time the independent impact of the proctoring program on the success of CTO recanalization procedures. The study determined prognostic factors such as the timeframe of the program and the number of procedures that may influence the achievement of the best possible educational results. Among the analyzed parameters, only the morphological characteristics of the occlusion (J-CTO score) and the proctor's support during the first 50 procedures, were independent factors influencing the effectiveness of recanalizations. Contrary to the results of the PROGRESS-CTO, RECHARGE, and CASTLE studies, in this analysis, clinical factors did not influence the effectiveness of the procedure. The criterion of the patient's age >65 years, considered prognostically unfavorable for the success and safety of the procedure, and the history of coronary revascularization, which are included in the scales determining the effectiveness of CTO recanalization, lost their importance, perhaps due to the importance of gaining experience in the proctoring program [23–26].

This is particularly important given that the population included in this analysis was clinically more burdened than the populations presented in the meta-analysis; it was older (65 vs. 60), with a more common history of hypertension (83% vs. 54%), diabetes (42% vs. 22%), dyslipidemia (61% vs. 52%), previous MI (50% vs. 40%), PCI (56% vs. 21%), and CABG (13% vs. 10%) [27]. On the other hand, our analysis of the significance of individual components of the J-CTO score was consistent with the results of the PROGRESS, RECHARGE, and CASTLE studies, indicating the strongest impact of the presence of massive calcifications and occlusion within the tortuous segment of the vessel [23–26].

The relatively low percentage of procedures on anatomically complex occlusions (J-CTO score ≥2) and procedures using the retrograde technique are unquestionable limitations of this study. Nevertheless, this characteristic of the studied group reflects the actual population of our center that begins the systematic introduction of this treatment technique.

Article information

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