New scoring system for predicting percutaneous coronary intervention of chronic total occlusion success: Impact of operator's experience

Mohsen Mohandes¹, Cristina Moreno¹, Mónica Fuertes¹, Sergio Rojas¹,
Alberto Pernigotti¹, Diego Zambrano, Victor Doblas¹,
Francisco Fernández¹, Jordi Guarinos¹, Alfredo Bardají²

¹Interventional Cardiology Unit, Cardiology Division, Joan XXIII University Hospital,
Pere Virgili Health Research Institute (IISPV), Tarragona, Spain

²Cardiology Division, Joan XXIII University Hospital, Pere Virgili Health Research Institute (IISPV),
Tarragona, Spain

Abstract

Background: Several scoring systems have been developed in order to predict percutaneous coronary intervention (PCI) result of chronic total occlusion (CTO). The scores principally include anatomic and clinical variables. Operator experience is a decisive factor for achieving successful result. We sought to assess the real impact of operator growing experience on CTO-PCI success.

Methods: The angiographic and clinical variables of CTO-PCIs performed in our center between May 2007 and April 2021 were collected, and variables with potential association with procedural result were thoroughly reviewed. The influence of operator experience based on the number of previous CTO-PCIs was statistically assessed. A scoring system with combination of anatomic variables and operator experience was devised.

Results: A total of 540 PCIs in 457 patients were performed in our institution. The scoring model was developed from the derivation set (2/3 of the cohort). The final variables in logistic regression model were CTO length ≥ 20 mm, blunt stump, vessel tortuosity $> 45^\circ$ and operator experience < 100 PCIs. The model showed good performance in the derivation set (area under curve [AUC]: 0.768; confidence interval [CI]: 0.706–0.830; $p < 0.001$) with no significant shrinkage in the validation set (AUC: 0.704; CI: 0.613–0.796; $p < 0.001$).

Conclusions: This new score (E-CTO score) adequately predict the probability of CTO-PCI failure. The model includes a variable representing operator experience along with other anatomic variables. (Cardiol J)

Key words: percutaneous coronary intervention, coronary occlusions, coronary arteries

Introduction

Although the proportion of patients undergoing percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) has increased over the last decade [1], PCIs on these kinds of inter-

vention continue to be challenging for interventionists, with lower procedural success rate and worse outcomes compared with other complex non-CTO-PCIs [2]. During the last decade several scoring systems have been devised to correlate angiographic and/or clinical variables with final PCI

Address for correspondence: Mohsen Mohandes, MD, Interventional Cardiology Unit, Cardiology Division, Joan XXIII University Hospital, Pere Virgili Health Research Institute (IISPV), Calle Dr Mallafre Guasch 4, 43007 Tarragona, Spain, tel: 0034-977295817, e-mail: mohandesmohsen@hotmail.com

Received: 7.07.2021

Accepted: 11.08.2021

Early publication date: 23.09.2021

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success [3–6] aimed to stratify procedure difficulty for operators dealing with a CTO. Although some anatomic features such as CTO length ≥ 20 mm, blunt stump and calcification, are commonly related to the procedural success in different scoring system [3, 6], CTO-PCI is highly operator dependent in such a way that more seasoned operators can achieve a high level of success in more complex cases [7].

Operator expertise is something that has been presupposed in different scoring systems but its real impact as an independent factor for CTO-PCI success has not yet been adequately scrutinized and the information in this regard is scarce in literature. We sought to assess the predictive variables for CTO-PCI success in our entire cohort since the installation of the program in our institution, including the contribution of operator experience as a potential independent factor.

Methods

The CTO program was established in our institution in May 2007, with a lower volume of interventions during its initial steps and at least 50 procedures a year since 2013. Five workshops with Japanese experts in CTO-PCI over 5 consecutive years were carried out in our hospital, aiming to improve the experience of local operators. A CTO was defined as the presence of a coronary artery obstruction with absent antegrade flow through the lesion (thrombolysis in myocardial infarction [TIMI] grade 0 flow standing for more than 3 months [8]). All data related to the procedures including those angiographic variables with potential influence on the procedural result were prospectively introduced in our database. The angiographic variables were re-examined again by 2 members of our cath lab. In case of discrepancy the opinion of a third examiner was requested and a final consensus was established.

A blunt stump was defined as absence of tapered tip or dimple at the entry point of the CTO, indicating the direction of the true lumen. Calcification was considered if any evident calcification was detected in CTO segment regardless of its severity. The attribution of tortuosity was based on the presence of bending $> 45^\circ$ within CTO segment. CTO length was measured in therapeutic procedure while collaterals supplied the CTO distal segment which is more representative of true distance of the occlusion [9].

Upon completing the review, 50 randomly selected cases were inspected and the level of concordance between 2 observers was estimated

so as to assess and resolve any possible interobserver bias.

Double access was employed in case of contralateral collateral supply to the CTO, with radial approach for the contralateral injection used in the majority of cases. The antegrade approach was the preferred strategy especially during the initial steps of our experience and retrograde access was incorporated as the level of expertise increased in our center. Retrograde approach was defined when an attempt was made to cross collateral channels supplying the distal part of the occluded vessel retrogradely [10]. Technical success was defined as achievement of TIMI grade 2 or greater antegrade flow in all ≥ 2.5 mm distal branches with $< 30\%$ residual stenosis of the target CTO lesion at procedure end [8].

With the exception of few cases, the vast majority of CTO-PCIs were performed by a single dedicated operator.

Complications such as in-hospital death, periprocedural myocardial infarction (MI), coronary perforation requiring pericardiocentesis, major vascular complications needing percutaneous or surgical intervention and stroke were reported. Peri-procedural MI assignment was in accordance with the universal definition of PCI-related MI [11]. All patients signed informed consent before undergoing the procedure.

Statistical analysis

Continuous variables were presented as mean $\pm$ standard deviation and categorical variables were expressed as absolute numbers and percentages. The Student t statistic was used to compare quantitative variables between two groups and the χ^2 or Fisher exact test were applied as appropriate to evaluate the association between qualitative variables. Based on the gradual improvement in the procedural success over time especially after first block of 100 cases, a binary variable of PCIs number more or less than 100 was created in order to assess the influence of accumulative experience on the final success. The entire cohort was randomly divided into derivation and validation sets at a ratio of 2:1. Odds ratios (ORs) of angiographic and clinical variables with a plausible relation to procedural failure such as CTO stump, bending, CTO length, calcification, previous failed attempt, ostial location, target vessel, distal vessel visibility, vessel diameter < 2.5 mm, age, sex, previous MI, previous coronary artery bypass grafting (CABG) and multivessel disease [3, 4, 12–14], were individually assessed and those with a $p < 0.10$ were

selected for introducing in the multivariate model. Even if the p value for candidate variables was not statistically significant but had an OR greater than or equal to 1.2, the variable was kept in the model due to its potential plausible contribution to the model performance. A predictive model with a combination of variables associated with procedural failure with multivariate logistic regression was constructed using both forward and backward step-wise methods in the derivation model. A scoring model was developed in the derivation set giving 1 point to each variable remaining in the multivariate logistic regression model according to their magnitude of beta coefficient. The performance of the model was assessed by the receiver operator characteristic (ROC) curve. The discriminatory performance of the model was validated by comparing the ROC curve of the derivation set with that of the validation set. A linear trend in categorical variables was evaluated by the polynomial test in the logistic regression model.

The goodness-of-fit of the model was estimated using the Hosmer and Lemeshow test in order to evaluate any possible discrepancy between observed and expected values.

Finally, a prognostic index statistic model was developed with different combinations of predictive variables so as to assess the relative risk of procedural failure in fictitious individuals. Statistical package of SPSS 19 was used for all analysis and a p value of < 0.05 was considered to indicate statistical significance.

Results

A total of 540 PCIs in 457 patients between May 2007 and April 2021 were performed at the cited institution. The average age of the entire cohort was 65 ± 10 years old and 246 (45.6%) patients had diabetes. In 1 patient, there were missing values with regard to some angiographic variables related to procedural success. The level of interobserver concordance (kappa index) in 50 randomly selected cases for the estimation of variables associated with the procedural result was 0.8.

Out of 492 first-attempt CTO-PCIs, 394 (80.1%) were successful. A total of 48 new-attempts on previously failed procedures were carried out of which 36 (75%) were successful. The overall procedural success by patient and artery was 86% in the entire cohort (Fig. 1). The success rate improved over time especially after the first block of 100 cases with a significant p for linear trend ($p < 0.001$; Fig. 2).

Figure 1. Flowchart of overall procedural success including reattempted interventions in the entire cohort; CTO — chronic total occlusion; PCI — percutaneous coronary intervention.

Figure 2. Procedural success rate according to growing case performance in the entire cohort.

Comparison of baseline, angiographic characteristics and procedural outcomes in failed and successful groups in the derivation set is depicted in Table 1. The failed group was represented by significantly more complex lesions according to J-CTO score (2 ± 1.1 vs. 1.1 ± 1 ; $p < 0.001$) with regard to the successful group. Both procedural and

Table 1. Comparison of baseline, angiographic characteristics and outcomes between successful and failed procedures in derivation group.

	Successful procedure (n = 285)	Failed procedure (n = 76)	P
Age [years]	64.6 ± 11.1	63.9 ± 10.6	0.65
Female	47 (16.5%)	7 (9.2%)	0.11
BMI [kg/m ²]	28.6 ± 4.6	28.6 ± 4.2	0.9
Hypertension	210 (73.7%)	59 (77.6%)	0.48
Diabetes	128 (44.9%)	37 (48.7%)	0.56
Dyslipidemia	192 (67.4%)	60 (78.9%)	0.051
Smoking	167 (58.6%)	48 (63.2%)	0.47
Previous MI	123 (43.2%)	37 (48.7%)	0.39
Previous CABG	23 (8.1%)	7 (9.2%)	0.75
MD	180 (63.2%)	49 (64.5%)	0.83
Target vessel:			0.33
LAD	150 (34.9%)	28 (25.5%)	
LCX	80 (18.6%)	19 (17.3%)	
RCA	187 (43.5%)	62 (56.4%)	
DG	6 (1.4%)	1 (0.9%)	
LM	2 (0.5%)	0 (0%)	
RI	3 (0.7%)	0 (0%)	
SVG		2 (0.5%)	0 (0%)
Ejection fraction < 40%	45 (15.8%)	11 (14.5%)	0.78
J-CTO score	1.1 ± 1	2 ± 1.1	< 0.001
E-CTO score	0.77 ± 0.88	1.76 ± 1	< 0.001
Easy	135 (47.5%)	10 (13.2%)	
Intermediate	94 (33.1%)	18 (23.7%)	
Difficult	40 (14.1%)	29 (38.2%)	
Very difficult	15 (5.3%)	19 (25%)	
Retrograde*	31 (10.8%)	24 (31.6%)	< 0.001
Procedure time [min]	145 ± 73	200 ± 80	< 0.001
Fluoroscopy time [min]	64 ± 42	103 ± 42	< 0.001
Contrast medium	251 ± 99	271 ± 98	0.13
In-hospital death	2 (0.7%)	1 (1.3%)	0.51
Perforation	0 (0%)	2 (2.6%)	0.04
MV complication	3 (1.1%)	0 (0%)	1
MI	2 (0.7%)	6 (7.9%)	< 0.001

*The retrograde approach in the entire cohort was 15.4%. BMI — body mass index; CABG — coronary artery bypass graft; DG — diagonal artery; E-CTO — operator experience-chronic total occlusion; LAD — left anterior descending coronary artery; LCX — left circumflex; LM — left main; MI — myocardial infarction; MD — multivessel disease; MV complication — major vascular complication; RCA — right coronary artery; RI — ramus intermedius; SVG — saphenous vein graft

fluoroscopy time were significantly longer in the failed group compared with those of the successful group (200 ± 80 vs. 145 ± 73 min and 103 ± 42 vs. 64 ± 42 min, respectively).

The comparison of baseline, clinical and angiographic characteristics as well as procedural outcomes between derivation and validation sets revealed no significant between-group-difference (Table 2). The right coronary artery was the most

frequently targeted artery representing 166 (46%) and 83 (46.4%) cases in derivation and validation groups, respectively.

Those variables potentially related with technical success are depicted in Table 3. Those variables with $p < 0.10$ and/or $OR \geq 1.2$ were selected for the subsequent analysis in the multivariate model.

In the logistic regression model the final variables using both forward and backward stepwise

Table 2. Baseline patient characteristics, angiographic characteristics and procedural outcomes comparison between derivation and validation groups.

	Derivation set (n = 361)	Validation set (n = 179)	P
Age [years]	64.5 ± 11	66.4 ± 10.6	0.053
Female	54 (15%)	30 (16.8%)	0.6
BMI [kg/m ²]	28.6 ± 4.5	29.11 ± 4.9	0.25
Hypertension	92 (25.5%)	44 (24.6%)	0.82
Diabetes	196 (54.3%)	98 (54.7%)	0.92
Dyslipidemia	109 (30.2%)	49 (27.4%)	0.5
Smoking	215 (59.6%)	107 (59.8%)	0.96
Previous MI	160 (44.3%)	85 (47.5%)	0.49
Previous CABG	30 (8.3%)	13 (7.3%)	0.67
MD	229 (63.4%)	114 (63.7%)	0.95
Target vessel:			0.94
LAD	119 (33%)	59 (33%)	
LCX	65 (18%)	34 (19%)	
RCA	166 (46%)	83 (46.4%)	
DG	5 (1.4%)	2 (1.1%)	
LM	2 (0.6%)	0 (0%)	
RI	3 (0.8%)	0 (0%)	
SVG	1 (0.3%)	1 (0.6%)	
Ejection fraction < 40%	56 (15.5%)	24 (13.4%)	0.52
J-CTO score	1.31 ± 1.11	1.33 ± 1.14	0.84
E-CTO score	1 ± 0.99	1 ± 0.96	0.83
Retrograde	54 (15.2%)	28 (15.6%)	0.44
Procedure time [min]	157 ± 78	151 ± 67	0.4
Fluoroscopy time [min]	71 ± 45	71 ± 44	0.97
Contrast medium	256 ± 99	249 ± 76	0.43
Procedural success	285 (78.9%)	145 (81%)	0.57
In-hospital death	3 (0.8%)	0 (0%)	0.55
Perforation	2 (0.6%)	1 (2.6%)	1
MV complication	3 (0.8%)	0 (0%)	0.55
MI	8 (2.2%)	4 (2.2%)	1

BMI — body mass index; CABG — coronary artery bypass graft; DG — diagonal artery; E-CTO — operator experience-chronic total occlusion; LAD — left anterior descending coronary artery; LCX — left circumflex; LM — left main; MI — myocardial infarction; MD — multivessel disease; MV complication — major vascular complication; RCA — right coronary artery; RI — ramus intermedius; SVG — saphenous vein graft

methods were CTO length ≥ 20 mm, blunt stump, vessel tortuosity $> 45^\circ$ and accumulative experience less than 100 CTO-PCIs (Table 4). E-CTO score was derived from variables remaining in the multivariate model. As the magnitude of beta coefficient was close to unit, 1 point was given to each variable. The score classified the CTO as easy (0 point), intermediate (1 point), difficult (2 points) and very difficult (≥ 3 points).

Receiver operator characteristic analysis of the model showed good performance in derivation set (area under curve [AUC]: 0.768; CI: 0.706–0.830; $p < 0.001$) with no significant shrink-

age in validation set (AUC: 0.704; CI: 0.613–0.796; $p < 0.001$). Additional assessment of AUC represented in ROC curve for variables included in J-CTO model was performed with AUC: 0.747 (CI: 0.68–0.81; $p < 0.001$) for derivation and AUC: 0.617 (CI: 0.51–0.72; $p = 0.034$) for validation set, respectively (Fig. 3).

The model showed good calibration both in derivation and validation groups according to the Hosmer and Lemeshow test (X^2 : 1.84; p : 0.87 for derivation and X^2 : 9.23; p : 0.16 in validation group, respectively).

According to the present study scores the probability of PCI failure increased from class 0 to

Table 3. Preselection of variables in univariate model as a previous step for the construction of the multivariate model. Variables with $p < 0.10$ and/or odds ratio ≥ 1.2 were kept in the model for the subsequent multivariate statistical analysis.

Variables	Odds ratio (95% CI)	Beta coefficient	P
Length	3.07 (1.79–5.26)	1.12	< 0.001
Stump	3.9 (2.35–6.76)	1.38	< 0.001
Tortuosity	4.2 (2.42–7.25)	1.43	<0.001
CN	2.4 (1.31–4.41)	0.88	0.004
Calcification	1.4 (0.82–2.33)	0.34	0.19
Sex	1.95 (0.84–4.5)	0.67	0.12
Previous MI	1.25 (0.75–2.07)	0.22	0.39
Ostial location	1.22 (0.53–2.83)	0.20	0.64
Previous attempt	1.34 (0.55–3.30)	0.29	0.52
Visibility	1.74 (0.73–4.18)	0.56	0.21
Diameter < 2.5 mm	1.25 (0.72–2.16)	0.22	0.43
Age	0.99 (0.97–1.01)	–0.005	0.65
CABG	1.15 (0.48–2.80)	0.14	0.75
MD	1.06 (0.62–1.8)	0.057	0.83
Artery	1.07 (0.85–1.36)	0.071	0.56

CABG — coronary artery bypass graft; CI — confidence interval; CN — case number; MD — multivessel disease; MI — myocardial infarction

Table 4. Variables associated with CTO-PCI failure in multivariate logistic regression model derived from derivation subset. Four independent predictors were identified by the forward and backward method: chronic total occlusion length ≥ 20 mm, blunt stump, bending $> 45^\circ$ and accumulative experience < 100 cases ($n = 360$). E-CTO score was derived from variables remaining in the multivariate model giving one point to each variable as the magnitude of beta coefficients was close to unit.

Predictors	Odds ratio (95% CI)	Beta coefficient	P	E-CTO score
Length	2.06 (1.13–3.7)	0.723	0.018	1
Stump	3.69 (2.0–6.69)	1.3	< 0.001	1
Tortuosity	2.67 (1.47–4.8)	0.98	0.001	1
CN	3.20 (1.61–6.3)	1.16	0.001	1

CI — confidence interval; CN — case number; E-CTO score classification: 0 = easy; 1 = intermediate; 2 = difficult; ≥ 3 = very difficult

3 (easy to very difficult CTO) with significant p for linear trend both in derivation and validation sets ($p < 0.001$; Fig. 4).

Prognostic index derived from the combination of different values of 4 variables in fictitious individuals predicts a relative risk (RR) of 1 for the case with 0 points for all 4 independent variables (the easiest case). If a fictitious case has 1 point in all 4 variables, the RR of failure is 11.4 times more with respect to the easiest case (Table 5).

Discussion

In this single center experience in CTO-PCIs the independent predictors associated with the

procedural failure were CTO blunt stump, the occlusion length ≥ 20 mm, tortuosity $> 45^\circ$ in addition to the operator's accumulative experience. The study reveals operator expertise, defined as less than 100 previous CTO-PCIs performance, as an independent predictor for the procedural failure.

The construction of scoring systems in CTO-PCI are aimed to predict and correlate the level of procedural difficulty with final procedural result. Scoring systems provide interventionists with a quantitative measure of procedural difficulty and the final success rate, which is beneficial when planning a PCI. Moreover, the CTO scoring models enable us to tailor the case difficulty to the operator level of experience so that more complex cases

Figure 3. Receiver operator characteristic (ROC) curve in derivation (A) and validation (B) sets based on variables included in E-CTO (CTO length, stump, bending and operator experience) and ROC curve in derivation (C) and validation (D) sets based on variables included in J-CTO score (CTO length, stump, bending, calcification and previous failed attempt); CTO — chronic total occlusion; AUC — area under curve; CI — confidence interval.

could be performed with more seasoned operators [15]. Many scoring models mainly encompass anatomic variables such as calcification, ambiguous stump, CTO length and bending. Other scores found the association between CTO-PCI failure and several clinical variables including previous MI, previous CABG and age in addition to anatomic variables [12, 13].

What is commonly assumed in different scoring systems, is the fact that the submitted cases were performed by expert operators as it is specifically mentioned in the Euro-CTO castle score [13]

which analyzed the outcome of 20,000 CTO-PCIs in centers with more than 50 cases a year.

As mentioned earlier, CTO-PCIs are highly operator-dependent. According to the Euro-CTO club registry, operators who have performed more than 300 CTO-PCIs and maintain an annual procedure number of at least 50 cases can achieve a success rate of more than 85% [16].

Zein et al. [17] analyzed the association of operator experience in CTO-PCI success according to previous case number performance at the time of CTO-PCI (< 12, between 12 and 33, and

Figure 4. Probability of percutaneous coronary intervention success according to the magnitude of E-CTO score in derivation and validation set.

Table 5. Prognostic index: elaboration of fictitious subjects with different combinations of unfavorable predictors for CTO-PCI success and their relative risk (RR) for procedural failure.

Length	Stump	Bending	CN	Prop	RR
0	0	0	0	0.0690	0.9993*
0	0	1	0	0.1097	1.5892
1	0	0	0	0.1354	1.9617
0	0	0	1	0.2025	2.9343
1	0	1	0	0.2066	2.9937
0	1	0	0	0.2332	3.3796
0	0	1	1	0.2969	4.3024
0	1	1	0	0.3359	4.8678
1	0	0	1	0.3492	5.0613
1	1	0	0	0.3913	5.6709
1	0	1	1	0.4716	6.8346
0	1	0	1	0.5104	7.3970
1	1	1	0	0.5167	7.4882
0	1	1	1	0.6342	9.1912
1	1	0	1	0.6878	9.9688
1	1	1	1	0.7856	11.3858

*Reference value. According to this index if a patient has none of the unfavorable predictors the relative risk of procedural failure is almost 1 (the easiest and the reference case) and if all four unpropitious predictors are present the relative risk increases by 11.4 times (the most unfavorable case) with regard to the referent case. CN — case number (< 100 PCIs = 1); Prop — the failure probability

≥ 34). CTO-PCI success rate increased significantly throughout these 3 tertiles (44.9%, 54.5% and 64.5%) respectively according to this study.

Japanese CTO-PCI expert registry reported results of CTO-PCIs performed by 41 highly experienced operators [18] with a high technical success (89.9%) and a frequent selection of the retrograde approach (in 27.8% of cases) as the first strategy. The study indicates that highly seasoned operators are more familiar with more complex techniques such as the retrograde approach, enabling them to achieve a high technical success rate. It is worth mentioning that the retrograde approach in the current entire cohort was lower than that reported in the Japanese study and accounted for 15.4% of cases which reveals the fact that more complex techniques were incorporated gradually as experience increased over time.

Habara et al. [19] compared the CTO-PCIs success rate in high-volume centers (> 50 CTO-PCIs per year) with that of low-volume centers (< 50 CTO-PCIs per year) in Japan and found a statistically significant between-group difference (90.6% vs. 85.6%, respectively). They concluded that operator experience was a key factor for this disparity.

Therefore, the impact of operator experience on CTO-PCI technical success is something that is commonly accepted but its influence and impact on a scoring system not have been previously addressed to date. Based on this rationale and in agreement with our progressive improvement in CTO-PCIs it was considered plausible to include the operator expertise along with angiographic

variables in a scoring model. Although adjusted to the reality of our center in terms of logistic and technical strategies, the scoring model could acceptably predict the probability of PCI failure in the cohort. Results were consistent with the evidence in literature regarding a clear impact of operator experience on CTO-PCI outcomes, which we expressed and confirmed in a scoring model with a statistical base.

As previously reported the J-CTO score fitness for technical success prediction in the present cohort, as characterized by growing experience over time it was concluded that the score showed better performance as the level of experience increased [20]. Indeed, the inclusion of operator experience as an independent predictor in a new devised scoring system (E-CTO score) improved the performance of the model comparing with J-CTO score as depicted in ROC curves earlier (Fig. 3). The scoring model predicts acceptably the procedural result and the elaboration of prognostic index provides additional information about the relative risk of PCI failure in each case based on the combination of values of different variables. This information can be shared with the patient and referring physician before proceeding with the intervention.

Limitations of the study

There are several limitations in this study. Firstly, this is a single center study with cases performed mainly by a single operator and although the study has internal validation, its results cannot be extrapolated to other centers. Therefore, the study needs external validation in centers with similar logistic and technical characteristics in terms of CTO-PCIs. Secondly, the incorporation of more complex techniques such as the retrograde approach was gradual in our institution and not in the first step of our CTO-PCI program. Increased application of retrograde approach might have changed the results. As mentioned previously, in the Japanese series retrograde approach was used more frequently than in the present cohort. Thirdly, improvement and incorporation of new devices for CTO-PCI over time probably is another contributing factor for procedural success, and was not scrutinized in the current study. Finally, the use of antegrade dissection reentry with dedicated devices such as the CrossBoss catheter, Stingray balloon and wires (Boston scientific, Natick, Massachusetts) that could have made the procedure faster [21, 22] was limited by operator experience in very few cases. Consequently, the results cannot

be extrapolated from the present center to centers in which this technique is more frequently used.

Conclusions

This new scoring system called E-CTO score comprising anatomic variables such as blunt stump, tortuosity $> 45^\circ$, CTO length ≥ 20 mm, along with operator previous experience < 100 CTO-PCIs shows a good prediction capacity for technical success with an AUC > 0.7 . The study has for the first time included operator experience in a scoring model, which can serve as a guide for centers with a dedicated CTO program with growing experience in this field.

Conflict of interest: None declared

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