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# Retrograde Chronic Total Occlusion Percutaneous Coronary Interventions

## Predictors of Procedural Success From the ERCTO Registry

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## ABSTRACT

**OBJECTIVES** The aim of this study was to identify independent predictors of procedural success after retrograde chronic total occlusion (CTO) percutaneous coronary intervention (PCI).

**BACKGROUND** Retrograde CTO PCI is an established technique, but predictors of success remain poorly understood.

**METHODS** A multivariable logistic regression model was used to analyze potentially important demographic, clinical, anatomical, and technical aspects of retrograde CTO PCI cases uploaded to the multicenter European CTO (ERCTO) Club Registry.

**RESULTS** In calendar years 2018 and 2019, 2,364 retrograde CTO PCI cases constituted the primary analysis cohort. A primary retrograde strategy was used in 1,953 cases (82.6%), and an initial antegrade approach was converted to retrograde in 411 cases (17.4%). Procedural success was achieved in 1,820 cases (77.0%) and was more likely to occur after a primary retrograde attempt versus conversion from an initial antegrade approach (80.9% vs 58.4%; $P < 0.0001$). After multivariable analysis, an absence of lesion calcification (OR: 1.86; 95% CI: 1.37-2.51; $P < 0.0001$), a higher degree of distal vessel opacification (OR: 2.47; 95% CI: 1.72-3.55; $P < 0.0001$), little or no proximal target vessel tortuosity (OR: 1.84; 95% CI: 1.28-2.64; $P = 0.001$), Werner collateral connection CC1 (OR: 4.87; 95% CI: 2.90-8.19; $P < 0.0001$) or CC2 (OR: 5.33; 95% CI: 3.02-9.42; $P < 0.0001$), and the top tertile of operator volume (>120 cases over 2 years) (OR: 1.88; 95% CI: 1.26-2.79; $P = 0.002$) were associated with the greatest chance of achieving angiographic success.

**CONCLUSIONS** Less calcification with good distal vessel opacification, little or absent proximal vessel tortuosity, and visible collateral connections, along with high-volume operator status, were all independently predictive of angiographically successful retrograde CTO PCI. (J Am Coll Cardiol Intv 2022;15:834-842) © 2022 by the American College of Cardiology Foundation.


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Adoption of a novel retrograde approach to recanalize a left anterior descending coronary artery chronic total occlusion (CTO) with a saphenous vein graft was first described in 1990.[1] Since then, retrograde CTO percutaneous coronary intervention (PCI) has gained widespread traction in the hands of experienced operators. Collectively they are spearheading a progressive maturation of iterative techniques to treat complex CTO lesions via coronary bypass grafts or septal and epicardial collateral vessels supported by the development of dedicated guidewires, microcatheters, and balloons.[2]

SEE PAGE 843

Observational analyses of registries from high-volume centers in Europe, the United States, and Asia have all shown increasing adoption of the technique in concert with high success rates, an acceptably low frequency of complications, and favorable mid- to long-term outcomes.[3-6] There is, however, a notable paucity of studies designed to delineate baseline variables that may confer a greater chance of procedural success using the retrograde CTO PCI approach. As the technique becomes increasingly embedded in the CTO playbook, ever more experienced operators have overcome the learning curve, thus permitting a more robust analysis of the data accrued along the way. We therefore proceeded to analyze the demographic, clinical, anatomical, and technical aspects of retrograde CTO PCI procedures extracted from the European CTO (ERCTO) Club Registry in order to identify factors that could predict an angiographically successful outcome.

## METHODS

**POPULATION.** Since 2008, ERCTO club members have prospectively recorded an extensive array of baseline demographics, angiographic findings, procedural data, and outcomes for every patient undergoing PCI using a retrograde and/or antegrade approach for ≥1 CTO lesion in epicardial coronary arteries (>2.5 mm) or coronary artery bypass grafts.[3,7] There are no exclusion criteria precluding the inclusion of all completed cases to the registry, with both successful and failed attempts available for scrutiny. For the present study we analyzed all entries from January 2018 to December 2019 to the EuroCTO Club dataset and included both primary retrograde CTO PCI attempts and those cases in which an initial antegrade strategy had failed, necessitating conversion to a retrograde approach during the same session or as an additional procedure. Given the observational construct of the study and the absence of all patient-identifying details in the registry, ethical approval was not required to undertake the investigation.

**ANATOMICAL DEFINITIONS.** These have been described previously and are summarized in Table 1.[7,8] Angiographic success was defined as a residual stenosis <10% and restoration of TIMI (Thrombolysis In Myocardial Infarction) flow grade 3 antegrade flow on completion of the procedure.

**STATISTICAL ANALYSIS.** Categorical data are presented as percentages, and comparisons were performed using the chi-square or Fisher exact test. Continuous variables are presented as mean ± SD for a normal distribution and as median (IQR) for a nonparametric distribution. Comparisons were made using a 2-sample Student's *t*-test or the Wilcoxon rank sum (Mann-Whitney) test.

From expert consensus and a study of the existing literature, a number of discrete, binary, and continuous variables thought to potentially influence angiographic outcome were extracted from the ERCTO dataset. These underwent univariable logistic regression to isolate the most important predictive factors of angiographic success from candidate variables that encompassed patient demographics, clinical characteristics, technical factors and anatomical features elucidated by invasive coronary angiography.

**ABBREVIATIONS AND ACRONYMS**

**CART** = controlled antegrade and retrograde tracking

**CTO** = chronic total occlusion

**PCI** = percutaneous coronary intervention

**TABLE 1 Definitions of Chronic Total Occlusion Anatomy as Mandated in the ERCTO Registry**

| Anatomy | Definition |
|---|---|
| Chronic total occlusion | A coronary occlusion present for >3 months with TIMI flow grade 0 |
| Lesion length | Visual estimation by angiography via single- or dual-contrast injections |
| Calcification of chronic total occlusion segment | Visual estimation by angiography<br>Mild: spots of calcium<br>Moderate: 50% calcification<br>Severe: >50% calcification |
| Tortuosity of the preocclusive segment | Straight: <70° bend<br>Moderate tortuosity: 2 bends >70° or 1 bend >90°<br>Severe tortuosity: ≥2 bends >90° or ≥1 bend >120° |
| Vessel stump | Tapered<br>Blunt<br>Unseen (ambiguous) |
| Werner classification of collateral connections | CC0: no continuous connection<br>CC1: threadlike continuous connection<br>CC2: side branch–like connection |
| Distal opacification | None<br>Faint<br>Good (ie, distal opacification comparable with proximal segment) |

ERCTO = European CTO Club; TIMI = Thrombolysis In Myocardial Infarction.

Thereafter, a multivariable logistic regression model was fitted incorporating "promising" variables ($P \leq 0.10$) emanating from the univariable analyses. The models considered were all logistic regression models in which the log odds of angiographic success after retrograde CTO PCI were regressed on several of these promising variables. Stepwise backward elimination was then applied until all remaining variables were found to be significant ($P \leq 0.05$). Multiple imputations were used to account for missing data for all exploratory factors of interest. Angiographic success as an outcome was available for all cases of primary retrograde and conversion to retrograde from a primary antegrade strategy. Statistical analysis was conducted using R version 3.6.1 (R Foundation for Statistical Computing).

Each operator uploading data to the registry is also required to list all peri- and postprocedural complications directly associated with and/or occurring during or after a retrograde CTO PCI attempt. However, complications were not incorporated into the univariate analysis, as their temporality precludes their use as preprocedural predictors of angiographic success. Moreover, a detailed study of the relationship between complications and operator, anatomical, demographic, and procedural variables is beyond the prespecified scope of the present analysis.

## RESULTS

There were 7,047 complete CTO PCI cases held by the 2018-2019 ERCTO Registry, performed by 57 operators working at 58 heart centers across Europe. Of these, 2,364 (33.5%) were conducted via the retrograde approach, which form the primary analysis cohort. Primary retrograde approach procedures constituted 1,953 cases (82.6%), and initial antegrade converted to retrograde represented 411 cases (17.4%). In total, 1,820 procedures (77.0%) were finished with angiographically successful results; 544 (23.0%) were unsuccessful. The reasons given for failure of the retrograde approach included wire not crossable, balloon not crossable, coronary perforation, no or slow flow, and persistent dissection. There were 54 cases (2.3%) in which a primary retrograde approach failed, but subsequent antegrade wiring resulted in an angiographically successful outcome.

**BASELINE VARIABLES.** All but 3 operators contributing to the dataset performed retrograde-approach CTO PCI. However, there was a bimodal distribution, with a small number of operators performing very many procedures. In contrast, there were 14 operators (25.9%) who performed fewer than 50 CTO procedures during the studied time interval. There was highly significant evidence that a retrograde-approach CTO PCI would result in a successful angiographic outcome with respect to total (antegrade and retrograde procedures) operator experience/volume ($P < 0.0001$ by the Kendall rank correlation test) (**Table 2**). This level of significance persisted when retrograde operator volume alone was tested ($P < 0.0001$ by the Kendall rank correlation test). A full breakdown of the analysis by operator volume can be found in the Supplemental Appendix. Diabetic status ($P = 0.02$), symptomatic angina ($P < 0.0001$), segmental regional wall motion abnormality related to a CTO lesion ($P = 0.0135$), and the CTO artery treated ($P = 0.049$) were also found to significantly influence procedural success (**Table 3**). A complete description of all the baseline variables explored is available in the Supplemental Appendix.

**PROCEDURAL CHARACTERISTICS.** There was a significantly reduced chance of angiographic success with cases that initially started with an antegrade approach (primary retrograde 80.9% vs initial antegrade 58.3%; $P < 0.0001$, chi-square test). Septal collateral vessels were the most frequently used retrograde pathway (n = 1,539, 83.0% success rate, 4.9% complication rate), followed by epicardial collateral vessels (n = 562, 77.2% success rate, 7.3% complication rate) and then bypass grafts (n = 92, 83.7% success rate, 3.3% complication rate). There was a significantly increased chance of angiographic success when septal, rather than epicardial, collateral vessels were used as the retrograde pathway (septal 83.0% vs epicardial 77.2%; $P = 0.0027$, chi-square test). In addition, filling collateral vessels (ie, ipsilateral vs contralateral vs retrograde vs bridging) ($P = 0.006$), collateral connections ($P < 0.0001$), extent of calcification ($P < 0.0001$), distal vessel opacification ($P < 0.0001$), severity of distal vessel disease ($P = 0.0001$), method of retrograde success ($P < 0.0001$), collateral pathway ($P = 0.009$), wire stiffness ($P < 0.0001$), J-CTO (Multicenter CTO Registry in Japan) score ($P = 0.0007$), and proximal vessel tortuosity were all shown to have significant effects on retrograde CTO PCI procedural success (**Table 4**). Retrograde crossing techniques most commonly used in order of frequency and success rate were reverse controlled antegrade and retrograde tracking (CART) (n = 866, 97.3% success), wire crossing (n = 569, 94.9% success), touching wire (n = 198, 86.4% success), GuideLiner-assisted reverse CART (n = 153, 98.7% success), subintimal knuckling followed by

**TABLE 2 Operator Volume and Retrograde Approach Outcome**

| Total Operator Volume From 2018 to 2019 | Retrograde CTO PCI Not Successful (n = 544)[a] | Retrograde CTO PCI Successful (n = 1,820)[a] | Total |
|---|---|---|---|
| Tertile 1: ≤50 procedures | 46 (34.1%) | 89 (65.9%) | 135 |
| Tertile 2: >50 to ≤120 procedures | 142 (30.5%) | 323 (69.5%) | 465 |
| Tertile 3: >120 procedures | 356 (20.2%) | 1,408 (79.8%) | 1,764 |
| Total | 544 | 1,820 | 2,364 |

| Summary statistics for total procedural CTO volume per operator over 2 y | | | | | |
|---|---|---|---|---|---|
| Minimum | First quartile | Median | Mean | Third quartile | Maximum |
| 1.0 | 43.0 | 76.0 | 123.6 | 134.0 | 745.0 |
| **Summary statistics for retrograde-only CTO volume per operator over 2 y[a]** | | | | | |
| Minimum | First quartile | Median | Mean | Third quartile | Maximum |
| 1.0 | 10.0 | 20.0 | 44.0 | 51.0 | 335.0 |

Values are n (%) unless otherwise indicated. [a]Includes both primary retrograde and initial antegrade converting to retrograde.
CTO = chronic total occlusion; PCI = percutaneous coronary intervention.

reverse CART (n = 91, 94.5% success), and CART (n = 11, 90.9% success). A complete description of all procedural and anatomical variables studied is available in the Supplemental Appendix.

**PROCEDURAL COMPLICATIONS.** Procedure-related death (n = 2), nonfatal myocardial infarction (n = 20), stent thrombosis (n = 5), nonfatal stroke (n = 2), coronary perforation causing tamponade or requiring surgical or percutaneous intervention (n = 35), dissection or thrombus of donor artery (n = 18), vascular complications (n = 15), vascular complications requiring surgical intervention (n = 9), hemoglobin reduction >3 g/dL (n = 11), blood transfusion of >2 U (n = 3), emergency redo PCI (n = 5), and emergency coronary artery bypass graft (n = 2) were observed in the primary analysis cohort. Retrograde CTO PCI attempts were therefore associated with a 5.4% complication rate overall.

**MULTIVARIABLE LOGISTIC REGRESSION.** The most significant independent predictor variables that offer the greatest chance of retrograde success were found to be lower levels of lesion calcification ($P < 0.0001$), a higher level of distal vessel opacification ($P < 0.0001$), lower proximal target vessel tortuosity ($P = 0.001$), Werner collateral connection classification CC1 ($P < 0.0001$) or CC2 ($P < 0.0001$),[9] and an operator in the top tertile of procedure volume conducting the CTO PCI ($P = 0.002$). ORs of the variables identified as independent predictors and their 95% CIs are presented in **Table 5 and Figure 1**. Good distal opacification, presence of collateral connections, and the highest tertile of operator volume were

**TABLE 3 Univariable Analysis of Selected Baseline Demographics of Individuals Undergoing Retrograde-Approach CTO PCI**

| | Retrograde CTO PCI Unsuccessful (n = 544) | Retrograde CTO PCI Successful (n = 1,820) | Relative Risk (95% CI) | *P* Value |
|---|---|---|---|---|
| Continuous variables | | | | |
| Age, y | 66.36 ± 9.89 | 64.14 ± 10.09 | | <0.0001 |
| Body mass index, kg/m$^2$ | 28.65 ± 4.59 | 28.66 ± 4.66 | | 0.97 |
| Baseline creatinine, μmol/L | 122.67 ± 95.54 | 131.25 ± 102.65 | | 0.074 |
| eGFR, mL/min/1.73 m$^2$ | 83.38 ± 39.54 | 82.93 ± 40.51 | | 0.82 |
| Occlusion duration, mo | 45.30 ± 60.92 | 41.60 ± 62.88 | | 0.44 |
| Binary variables | | | | |
| Peripheral vascular disease | 85 (15.6) | 200 (11.0) | 0.7 (0.6-0.9) | 0.004 |
| Diabetes mellitus | 200 (36.8) | 571 (31.4) | 0.9 (0.7-1.0) | 0.019 |
| Smoker | 300 (55.1) | 1,111 (61.0) | 1.1 (1.0-1.2) | 0.015 |
| Previous MI | 182 (33.5) | 525 (28.8) | 0.9 (0.8-1.0) | 0.043 |

Values are mean ± SD or n (%) unless otherwise indicated.
eGFR = estimated glomerular filtration rate; MI = myocardial infarction; other abbreviations as in Table 2.

**TABLE 4 Univariable Analysis of Selected Procedural Characteristics of Individuals Undergoing Retrograde-Approach CTO PCI**

| | Retrograde CTO PCI Unsuccessful (n = 544) | Retrograde CTO PCI Successful (n = 1,820) | OR (95% CI) | *P* Value |
|---|---|---|---|---|
| Continuous variables | | | | |
| Vessel diameter, mm | 3.03 ± 0.39 | 3.18 ± 0.43 | | <0.0001 |
| CTO length, mm | 36.90 ± 20.97 | 35.58 ± 19.05 | | 0.19 |
| Number of guidewires | 6.51 ± 5.06 | 6.25 ± 3.81 | | 0.27 |
| Total length of DES, mm | 80.98 ± 30.32 | 86.21 ± 30.57 | | 0.043 |
| Maximal diameter of DES, mm | 3.38 ± 0.52 | 3.46 ± 0.50 | | 0.11 |
| Binary variables | | | | |
| Wire externalization | 14 (2.6) | 1,439 (79.1) | 30.7 (18.3-51.6) | <0.0001 |
| Wire snaring | 5/543 (0.9) | 150 (8.2) | 9.0 (3.7-21.7) | <0.0001 |
| Proximal bend ≥ 45° | 231/411 (56.2) | 671/1,379 (48.7) | 0.9 (0.8-1.0) | 0.008 |
| Polymer wire | 173/520 (33.3) | 331/1,791 (18.5) | 0.6 (0.5-0.6) | <0.0001 |
| Conversion from primary antegrade approach | 171/226 (75.7) | 240/823 (29.2) | 0.4 (0.3-0.4) | <0.0001 |

Values are mean ± SD, n (%), or n/N (%) unless otherwise indicated.
DES = drug-eluting stent(s); other abbreviations as in Table 2.

found to have the greatest impact on procedural success. A full breakdown of the logistic regression model is available in the Supplemental Appendix.

A nomogram capturing the relative importance of each of these independent predictors and their contributions to an angiographically successful retrograde CTO PCI procedure has been formulated (**Central Illustration**). A worked example of the interplay among these predictors and the probability of success is outlined in **Figure 2**.

## DISCUSSION

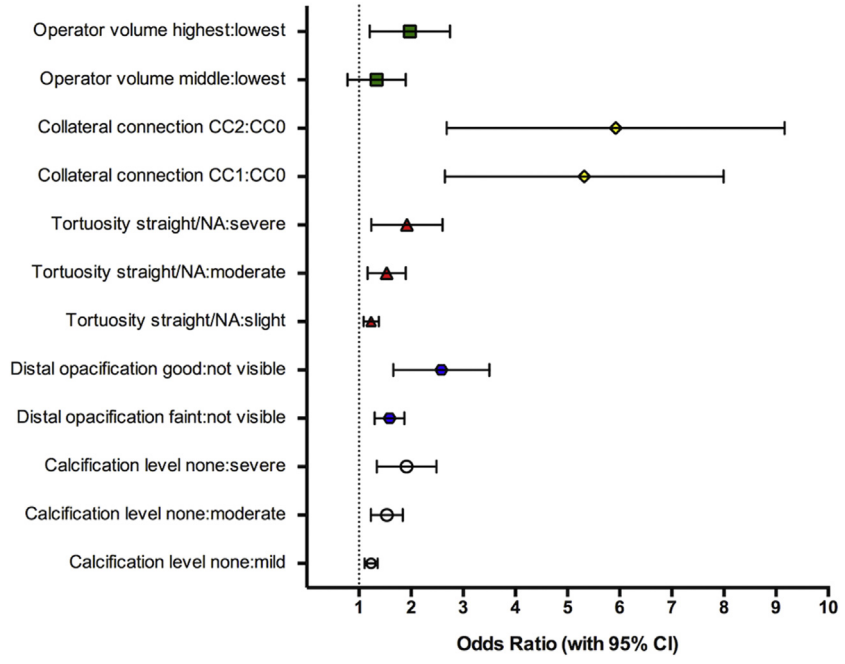
In this observational cohort analysis of all CTO PCI procedures prospectively uploaded to the ERCTO Registry in 2018 and 2019, we found that less lesion calcification, a higher degree of distal target vessel opacification, lower proximal vessel tortuosity, visible collateral connections, and a high-volume operator performing the retrograde approach technique were all independent predictors of angiographic success. To the best of our knowledge, this is the largest contemporary cohort of retrograde procedures to be analyzed for this specific purpose in the published research to date.[3,4,10,11] A previous study of the ERCTO Registry from January 2008 to December 2012, for instance, recorded just 1,582 retrograde procedures over a 5-year period, highlighting the rapid uptake and growing familiarity with this technique in recent years. This is the first time independent predictors of achieving angiographic success after specifically adopting a retrograde strategy have been sought and definitively identified from an appropriately sized sample population.[6,7,12-15] In contrast to the present analysis, Huang et al[12] found only greater size and lack of tortuosity of a collateral channel to be independently predictive of technical success when attempting retrograde CTO PCI. Their study sample, however, consisted of only 216 consecutive procedures performed by a single high-volume operator.

These independent variables are intuitive and primarily anatomical, and they will provide a robust foundation upon which to aid case selection of technically amenable CTO lesions, enhance the informed-consent process, and optimize preprocedural planning. Previous reports have established the premise that dedicated high-volume operators are more likely to achieve better outcomes after retrograde CTO PCI.[2,16,17] The present analysis is consistent with this, although procedural volume was not the most influential of the predictive variables.

**TABLE 5 Odds Ratios of Independent Predictor Variables Identified by the Final Multivariable Logistic Regression Model After Backward Elimination**

| | OR | 95% CI |
|---|---|---|
| Mild calcification | 1.23 | 1.11-1.36 |
| Moderate calcification | 1.51 | 1.24-1.85 |
| Severe calcification | 1.86 | 1.37-2.51 |
| Faint distal opacification | 1.57 | 1.31-1.88 |
| Good distal opacification | 2.47 | 1.72-3.55 |
| Slight proximal tortuosity | 1.23 | 1.09-1.38 |
| Moderate proximal tortuosity | 1.50 | 1.18-1.91 |
| Severe proximal tortuosity | 1.84 | 1.28-2.64 |
| Werner collateral connection CC1 | 4.87 | 2.90-8.19 |
| Werner collateral connection CC2 | 5.33 | 3.02-9.42 |
| Middle tertile of operator volume | 1.26 | 0.82-1.93 |
| Top tertile of operator volume | 1.88 | 1.26-2.79 |

**FIGURE 1** **Independent Predictors of Retrograde Chronic Total Occlusion Percutaneous Coronary Intervention Angiographic Success**




Forest plot of independently predictive variables, and their subcategorization, after multivariable logistic regression and backward elimination. In each case, the OR compares the given level of the variable with its lowest level. LCL = lower confidence limit; NA = not applicable; UCL = upper confidence limit.

Moreover, we chose our own arbitrary cutoffs for the tertiles of procedural volume in the present analysis given the lack of proscriptive guidance in the published research on what thresholds define a high-volume operator.[2]

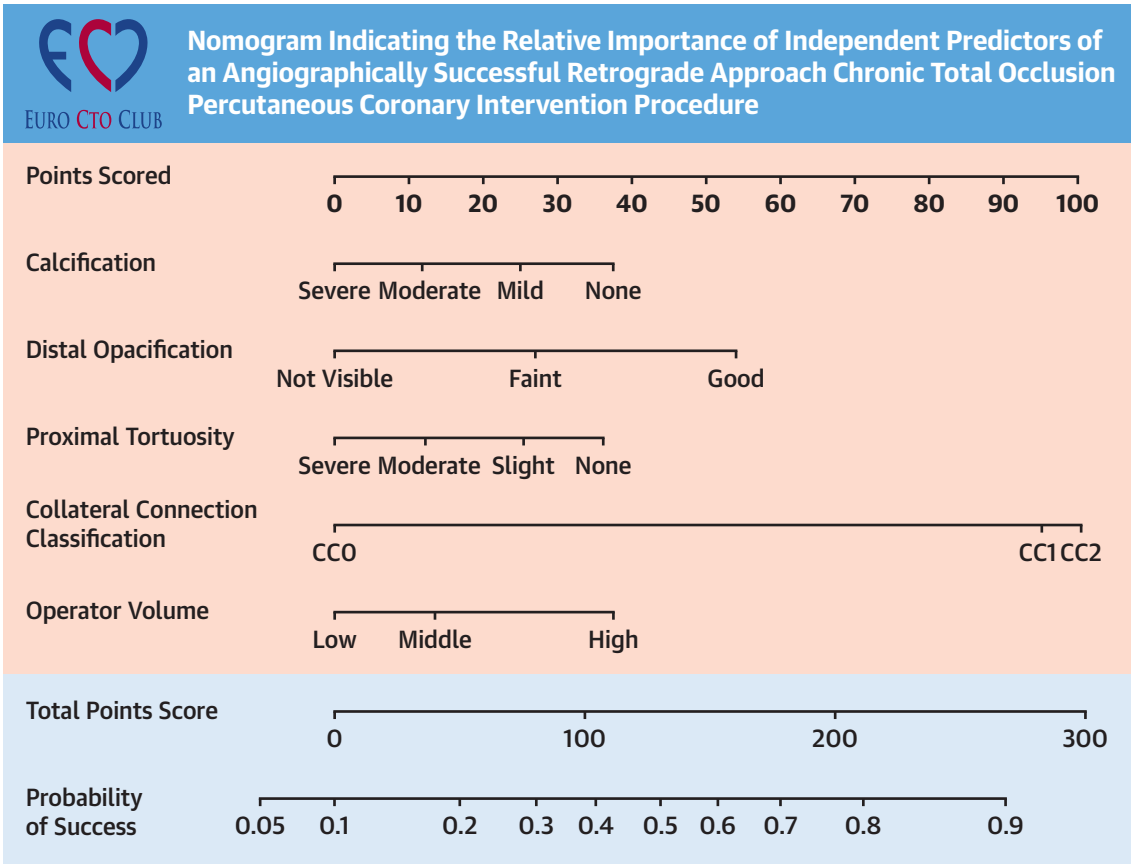
Of note, the J-CTO score, which is predominantly used to estimate the degree of difficulty for antegrade wiring of a CTO, did not reach the prerequisite level of significance to withstand the backward elimination of our multivariable regression model. This is despite previous studies' intimating a strong association with procedural efficiency and final angiographic success.[18,19]

Generic predictors of CTO recanalization are likely to be influenced by the most commonly used techniques. Indeed, more than two-thirds of the CTO PCIs accounted for by the registry were antegrade. When there are no antegrade options or those options are unlikely to succeed, it would seem reasonable to switch to or consider a retrograde strategy, supported by the findings from this analysis.

Given the specialist skill set required for retrograde CTO PCI and the dedicated array of contemporary guidewires and microcatheters available, it would seem plausible that a unique scoring system that can estimate the chances of procedural success could be developed for this specific lesion subset. The nomogram we have offered is hypothesis generating at best but does offer a tantalizing glimpse of what could be achieved with prespecified training and validation datasets of sufficient size and quality.

**STUDY LIMITATIONS.** All data were collected prospectively, but independent adjudication with review of the angiogram was performed in fewer than 10% of cases. This exposes our analysis to possible underreporting and publication bias. Ultimately, the accuracy of data uploaded to the registry rests on the individual operators. This also applies to the reporting of angiographic anatomical variables because, by its very nature, core laboratory analysis of this large multicenter registry was not available. Range checks to expose extreme

**CENTRAL ILLUSTRATION** **Independent Predictors of Successful Retrograde-Approach for Chronic Total Occlusion Percutaneous Coronary Interventions**




**Myat A, et al. J Am Coll Cardiol Intv. 2022;15(8):834–842.**

CC = collateral connection.

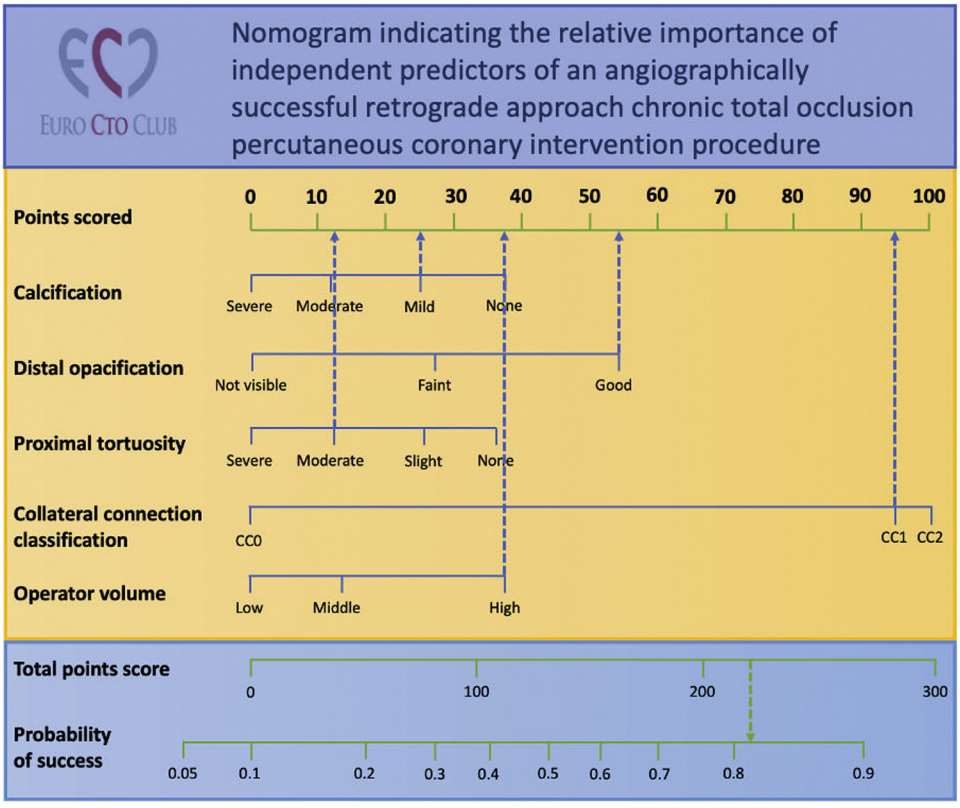
values and assessments of internal consistency were applied as integral parts of the data-cleaning process. Multiple imputation was used judiciously to account for missing data.

The absence of other promising variables, such as diabetes, ipsilateral and contralateral filling collateral vessels, and septal versus epicardial collateral vessels, from the fitted model should not be interpreted as meaning that they are unimportant. When carrying out a multivariable analysis, it is nearly always the case that there is correlation among the predictor variables, referred to as multicollinearity. This implies that just because a variable is not included in the "best" model does not mean that it is not predictive. The presence of multicollinearity, however, does not entirely prevent models from providing good predictions. Also, if care is taken about which variables to include, they can be instructive. In essence, this type of modeling should be regarded as hypothesis generating as opposed to establishing causal associations. Moreover, the emergence of extremely safe wires and microcatheters may negate any putative difference there may have been with respect to the type and flow of coronary collateral vessels.

## CONCLUSIONS

In this observational analysis of a large contemporary cohort of retrograde CTO PCI cases extracted from the ERCTO Registry, less lesion calcification, a higher degree of distal opacification, reduced proximal vessel tortuosity, visible collateral connections, and high-volume operator status were all

**FIGURE 2** **The ERCTO Nomogram for Independent Predictors of Procedural Success After Retrograde Chronic Total Occlusion Percutaneous Coronary Intervention**




Each postulated predictor variable can be evaluated and marked on the diagram with a vertical line drawn up to the "Points scored" axis at the top. The points scored for each variable are summed, and the total is marked on the "Total points score" axis in the lower bar. A vertical line is then drawn down to the "Probability of success" axis. Here mild calcification, good distal opacification, moderate tortuosity, CC1 class, and a high-volume operator will score approximately 215 points, which equates to a predicted probability of success of 0.82 (82%). CC = collateral connection; ERCTO = European CTO Club.

independently predictive of an angiographically successful procedural outcome.

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## PERSPECTIVES

**WHAT IS KNOWN?** CTO PCI via the retrograde approach is an established technique. Predictors of a successful angiographic outcome are, however, poorly characterized.

**WHAT IS NEW?** Analysis of the ERCTO Registry has shown that less lesion calcification, greater distal vessel opacification, reduced proximal vessel tortuosity, visible collateral connections, and high-volume operator status are independently predictive of procedural success.

**WHAT IS NEXT?** A fully validated risk score is needed to quantify the chances of a successful angiographic outcome after retrograde CTO PCI.

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**KEY WORDS** antegrade, chronic total occlusion, coronary collateral, percutaneous coronary intervention, retrograde

**APPENDIX** For supplemental statistical methods and the Strengthening the Reporting of Observational Studies in Epidemiology statement checklist of items that should be included in reports of cohort studies, please see the online version of this paper.