Predictors of Successful Hybrid-Approach (1) **Chronic Total Coronary Artery Occlusion Stenting**



An Improved Model With Novel Correlates

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ABSTRACT

OBJECTIVES The aim of this study was to develop a hybrid approach-specific model to predict chronic total coronary artery occlusion (CTO) percutaneous coronary intervention success, useful for experienced but not ultra-high-volume operators.

BACKGROUND CTO percutaneous coronary intervention success rates vary widely and have improved with the "hybrid approach," but current predictive models for success have major limitations.

METHODS Data were obtained from consecutively attempted patients from 7 clinical sites (9 operators, mean annual CTO volume 61 ± 17 cases). Angiographic analysis of 21 lesion variables was performed centrally. Statistical modeling was performed on a randomly designated training group and tested in a separate validation cohort. The primary outcome of interest was technical success.

RESULTS A total of 436 patients (456 lesions) met entry criteria. Twenty-five percent of lesions had prior failed percutaneous coronary interventions at the site. The right coronary artery was the most common location (56.4%), and mean occlusion length was 24 ± 20 mm. The initial approach was most often antegrade wire escalation (70%), followed by retrograde (22%). Success was achieved in 79.4%. Failure was most closely correlated with presence of an ambiguous proximal cap, and in the presence of an ambiguous proximal cap, specifically defined collateral score (combination of Werner and tortuosity scores) and retrograde tortuosity. Without an ambiguous proximal cap, poor distal target, occlusion length >10 mm, ostial location, and 1 operator variable contributed. Prior failure, and Werner and tortuosity scores alone, were only weakly correlated with outcomes. The basic 7-item model predicted success, with C statistics of 0.753 in the training cohort and 0.738 in the validation cohort, the later superior (p < 0.05) to that of the J-CTO (Multicenter CTO Registry of Japan) (0.55) and PROGRESS CTO (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention) (0.61) scores.

CONCLUSIONS Success can be reasonably well predicted, but that prediction requires modification and combination of angiographic variables. Differences in operator skill sets may make it challenging to create a powerful, generalizable, predictive tool. (J Am Coll Cardiol Intv 2017;10:1089-98) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

APC = ambiguous proximal cap

CTO = chronic total coronary artery occlusion

OR = odds ratio

PCI = percutaneous coronary intervention hronic total coronary artery occlusions (CTOs) are found in 15% to 30% of diagnostic catheterization procedures, are inconsistently treated with percutaneous coronary intervention (PCI), and are often the reason for referral for coronary artery bypass graft surgery (1-4). Improvements in angioplasty equipment, technique, and strategy (especially the

"hybrid approach," which is now the preferred strategy for many if not most experienced CTO operators [5]) have led to increased success rates for some operators in treating CTOs, but reported success rates continue to vary between 60% and 90% depending on the anatomy, the operator's experience, and willingness to take on difficult procedures (6-8). Current models to predict angiographic success in this situation are limited by only modest predictive value (C statistics ranging from 0.65 to 0.75) and are generally not specific to the hybrid approach (9-13). Given the risk and cost of the procedure, as well as varied physician expertise, better predictive models with contemporary strategies are needed.

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METHODS

PATIENTS ANALYZED. Clinical sites were chosen on the recommendation of leadership of the OPEN CTO (Outcomes, Patient Health Status, and Efficiency in Chronic Total Occlusion) study (14). Sites were asked to provide consecutive series of 40 to 80 patients from their recent experience, treated by 1 or more experienced hybrid operators, regardless of angiographic and clinical outcome. Patients were deidentified. Participation in this study was approved by the relevant local Institutional Review Board.

CLINICAL DATA. Clinical data were obtained directly from the clinical sites using dedicated case report forms.

ANGIOGRAPHIC ANALYSES. All angiographic analyses were performed by a single hybrid trained CTO operator, the Director of the Angiographic Core Laboratory at the Cleveland Clinic, using Siemens software and guide catheter calibration for quantitative measurements (15). All pre-intervention analyses were performed blinded to angiographic and clinical outcomes.

To assess reproducibility, 20 randomly selected angiograms were reviewed independently by 2

operators (S.G.E., R.N.) to assess concordance of selected morphological parameters, as reflected by Cohen's kappa statistic (>0.75 indicates strong agreement, 0.40 to 0.75 fair to good agreement, and <0.40 poor agreement).

SELECTED DEFINITIONS. Ambiguous proximal cap (APC) was defined as a flush occlusion with uncertainty as to the vessel's initial course and likely unwillingness of an experienced operator to use an aggressive wire to "stick" the cap. CTO was defined as a 100% stenosis with TIMI (Thrombolysis In Myocardial Infarction) flow grade ≤1 of presumably >3 months' duration.

Excessive proximal or retrograde tortuosity was defined as a $>90^{\circ}$ bend in diastole in a nonforeshortened projection in need of being traversed to access the CTO.

Interventional collateral vessels. Septal collateral vessels were graded for: 1) Werner classification (16), with grade 1 subdivided into 1A (definite but spindly, connecting with and filling all or much of the retrograde tree) and 1B (small but definitely present and filling a small portion of the coronary tree); 2) number of septal collateral vessels fulfilling at least Werner criterion 1B; 3) tortuosity score classification for the best interventional collateral vessel (0 = generally straight, 1 = moderate corkscrew without kinks, 2 = tight corkscrew and/or kinked); and 4) the presence or absence of a 90° turn into or out of the best intervention collateral vessel (17).

Other potential interventional collateral vessels were scored similarly, with the exception of number. On the basis of observations from the training cohort, a summary collateral risk score was defined as 0 = Werner 2 septal vessels, or Werner 2, tortuosity score <1 epicardial vessels, or bypass graft <90° access bend; 2 = Werner 0 septal vessels, or Werner 0 or tortuosity score 2 epicardial vessels, or bypass graft >120° access bend; and 1 = other.

Landing zones for dissection re-entry were graded on a scale of 0 to 2, with grade 2 indicating angiographically assessed >2 mm in diameter (not presumed on the basis of vessel size), >15 mm in length, no moderate to severe calcium, and no major side branches; grade 1 indicating 1 to 2 mm in diameter, >10 mm in length, and no severe calcium or major side branches; and grade 0 indicating anatomy less favorable than for a score of 1. Landing zones were also scored 0 or 1 for the presence of a side branch emanating from the landing zone supplying the left ventricle and with diameter >1.5 mm.

Lesion calcification was graded on a scale of 0 to 3: 0 = none visible, 1 = visible only with motion,

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