Validation of the OPEN-CLEAN Chronic Total Occlusion Percutaneous Coronary Intervention Perforation Score in a Multicenter Registry

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Coronary artery perforation is one of the most common and feared complications of chronic total occlusion (CTO) percutaneous coronary intervention (PCI). We evaluated the utility of the recently presented OPEN-CLEAN (Coronary artery bypass graft, Length of occlusion, Ejection fraction, Age, calcificatioN) perforation score in an independent multicenter CTO PCI dataset. Of the 2,270 patients who underwent CTO PCI at 7 centers, 150 (6.6%) suffered coronary artery perforation. Patients with perforations were older (69 ± 10 vs 65 ± 10, p <0.001), more likely to be women (89% vs 82%, p = 0.010), more likely to have history of previous coronary artery bypass graft (38% vs 20%, p <0.001), and unfavorable angiographic characteristics such as blunt stump (64% vs 42%, p <0.001), proximal cap ambiguity (51% vs 33%, p <0.001), and moderate-severe calcification (57% vs 43%, p = 0.001). Technical success was lower in patients with perforations (69% vs 85%, p <0.001). The area under the receiver operating characteristic curve of the OPEN-CLEAN perforation risk model was 0.74 (95% confidence interval 0.68 to 0.79), with good calibration (Hosmer−Lemeshow p = 0.72). We found that the CTO PCI perforation risk increased with higher OPEN-CLEAN scores: 3.5% (score 0 to 1), 3.1% (score 2), 5.3% (score 3), 7.1% (score 4), 11.5% (score 5), 19.8% (score 6 to 7). In conclusion, given its

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Funding: The authors are grateful for the philanthropic support of our generous anonymous donors and the philanthropic support of Mary Ann and Donald A Sens, Diane and Cline Hickok, Wilma and Dale Johnson, Charlotte and Jerry Golinvaux Family Fund, the Roehl Family Foundation, and the Joseph Durda Foundation. The generous gifts of these donors to the Minneapolis Heart Institute Foundation's Science Center for Coronary Artery Disease (CCAD) helped support this research project.

See page 34 for disclosure information.

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https://doi.org/10.1016/j.amjcard.2022.11.023

good performance and ease of preprocedural calculation, the OPEN-CLEAN perforation score appears to be useful for quantifying the perforation risk for patients who underwent CTO PCI. **(Am J Cardiol 2023;188:30−35)**

Coronary artery perforation occurs in approximately 5% of chronic total occlusion (CTO) percutaneous coronary intervention (PCI) and is one of the most feared complications of CTO PCI.[1−4] Determining the likelihood of complications facilitates the risk-benefit calculation and procedural planning in CTO PCI. In particular, coronary artery perforation is the most frequent and feared complication of CTO PCI.[5] Recently, Hirai et al[6] analyzed the OPEN-CTO (Outcomes, Patient health status, and Efficiency iN CTO hybrid procedures) registry and developed the OPEN-CLEAN (Coronary artery bypass grafting, Length of occlusion, Left ventricular Ejection Fraction [LVEF] <50%, Age, severe calcification) perforation score to predict the risk of angiographic coronary artery perforation. The risk score ranges from 0 to 7, with higher scores corresponding to a higher risk of perforation. This score showed good performance in the original dataset; however, external validation in larger datasets is important in assessing the generalizability of the score. We, therefore, sought to evaluate the performance of the OPEN-CLEAN perforation score in an independent dataset.

Methods

We evaluated the performance of the OPEN-CLEAN perforation score in a multicenter CTO PCI registry with 2,270 cases performed between 2009 and 2017 at 7 participating centers in Italy, Belgium, Japan, Spain, Canada, and the United States.

CTOs were defined according to the definition of CTO Academic Research Consortium as absence of anterograde flow through the lesion with a presumed or documented duration of ≥3 months.[7]

Calcification was assessed by angiography as mild (spots), moderate (involving <50% of the reference lesion diameter), or severe (involving ≥50% of the reference lesion diameter).

Technical success was defined as the successful canalization of the CTO vessel with <30% residual stenosis and final thrombolysis in myocardial infarction 3 flow.

Perforation was defined as contrast extravasation. Perforation requiring intervention was defined as the composite of covered stent implantation, balloon occlusion, and fat/coil embolization.

Major adverse cardiovascular events (MACEs) were defined as the composite of in-hospital death, stroke, periprocedural myocardial infarction, and cardiac tamponade requiring pericardiocentesis.

The OPEN-CLEAN perforation score was calculated[6] for each patient, and the discriminative capacity was assessed with the area under the receiver operating characteristic curve (AUC). The goodness-of-fit was assessed by the Hosmer−Lemeshow test.

Continuous variables were presented as mean ± SD and median (interquartile range) and compared using the independent *t* test or Mann−Whitney *U* test, as appropriate. Categorical variables were presented as absolute numbers and percentages and compared using chi-square or Fisher's exact test, as appropriate. Statistical analyses were performed using Stata v17.0 (StataCorp, College Station, Texas). The study was approved by the institutional review board of each site.

Results

In this dataset of 2,270 patients, mean age was 65 ± 10 years, most patients were men (89%), with a high prevalence of co-morbidities: diabetes mellitus (38%), previous coronary artery bypass grafting (CABG) (21%), and previous PCI (61%). The right coronary artery was the most common target vessel (50%), followed by the left anterior descending coronary artery (29%) and the left circumflex coronary artery (21%) (Table 1). Technical success was 84%. The incidence of MACE was 1.7% (n = 38), and patients who had a perforation were more likely to have other complications, including in-hospital death, MACE, stroke, and major bleeding (Table 1). The incidence of coronary artery perforation was 6.6% (n = 150) (Table 1). Of these perforations, 28 (19%) required intervention (representing 1.2% of the overall study population).

In this independent dataset, the corresponding perforation risk for OPEN-CLEAN score of 0 to 1 was 3.6%, reaching as high as 20% for OPEN-CLEAN score of 6 to 7, confirming that a higher OPEN-CLEAN score predicts a higher risk of coronary perforation (Figure 1). The AUC of the OPEN-CLEAN perforation risk model in our cohort was 0.74 (95% confidence interval [CI] 0.68 to 0.79) (Figure 2). The model showed good calibration (Hosmer −Lemeshow p = 0.72; Figure 3).

In our dataset, cardiac tamponade occurred in 12 (0.5%). OPEN-CLEAN score also had a good discriminative capacity to predict cardiac tamponade (AUC 0.75, 95% CI 0.58 to 0.92) with good calibration (Hosmer−Lemeshow p = 0.42).

Discussion

The main findings of our study are that in this independent multicenter registry of CTO PCI, (1) the OPEN-CLEAN perforation score had an acceptable discriminative performance (AUC 0.74), similar to that was reported by Hirai et al[6] (AUC 0.75) (Figure 2); and (2) the perforation risk percentages corresponding to each OPEN-CLEAN score were similar to what was previously reported (Figure 1).[6]

The OPEN-CLEAN score was based on 89 (8.9%) angiographic coronary artery perforations in a dataset of 1,000 patients.[6] Of these perforations, 43 (48%) were clinical (i.e., actionable) perforations.[6] The final model (OPEN-

Table 1
Characteristics and in-hospital clinical events of patients with and without perforation

Characteristics/procedural outcomes	Perforation (n = 150)	No perforation (n = 2,126)	p Value
Age, years	69 ± 10 (n = 150)	65 ± 10 (n = 2,125)	<0.001
Men, n	123 (82%)	1,890 (89%)	0.010
Hypertension, n	123 (83%)	1,610 (76%)	0.074
Dyslipidemia, n	132 (89%)	1,628 (80%)	0.013
Current smoker, n	22 (16%)	572 (28%)	0.003
Body mass index, kg/m^2	28.9 ± 5 (n = 149)	28.6 ± 7 (n = 2,058)	0.633
Diabetes mellitus, n	55 (37%)	798 (38%)	0.835
Peripheral arterial disease, n	10 (19%)	330 (19%)	0.989
Family history of premature coronary artery disease, n	42 (37%)	679 (35%)	0.576
Prior myocardial infarction, n	74 (52%)	952 (45%)	0.130
Prior heart failure, n	27 (18%)	438 (21%)	0.473
Prior percutaneous coronary intervention, n	98 (65%)	1,292 (61%)	0.271
Prior coronary artery bypass graft surgery, n	57 (38%)	417 (20%)	<0.001
Chronic pulmonary disease, n	11 (21%)	189 (11%)	0.022
Estimated glomerular filtration rate, mg/mmol	76 ± 22 (n = 142)	81 ± 26 (2,018)	0.010
Left ventricular ejection fraction, %	54 ± 11 (n = 143)	52 ± 12 (n = 2,032)	0.040
Blunt stump, n	96 (64%)	898 (42%)	<0.001
Proximal cap ambiguity, n	76 (51%)	652 (33%)	<0.001
Moderate/severe proximal tortuosity, n	43 (29%)	461 (22%)	0.048
Moderate/severe calcification, n	86 (57%)	913 (43%)	0.001
Lesion length (mm)			<0.001
<20	16 (11)	543 (26)	
20−60	66 (44)	1,104 (52)	
≥60	68 (45)	479 (23)	
J-CTO score	2.5 ± 1.2 (n = 150)	1.7 ± 1.2 (n = 2,123)	<0.001
PROGRESS-CTO score	1.2 ± 0.9 (n = 140)	1.1 ± 0.9 (n = 1,745)	0.124
CTO target vessel, n			0.169
Right coronary artery	89 (60%)	1,043 (49%)	
Left anterior descending	36 (24%)	614 (29%)	
Left circumflex	20 (13%)	396 (19%)	
Crossing strategy, n			
Antegrade wiring	18 (13%)	967 (54%)	<0.001
Antegrade dissection and re-entry	15 (11%)	288 (16%)	
Retrograde	101 (75%)	542 (30%)	
Technical success, n	103 (69%)	1,815 (85%)	<0.001
Procedure time, min	178 ± 74 (n = 145)	121 ± 68 (n = 1,744)	<0.001
Contrast volume, ml	357 ± 140 (n = 150)	308 ± 135 (n = 2,073)	<0.001
Fluoroscopy Time, min	74 ± 36 (n = 148)	47 ± 31 (n = 1,773)	<0.001
In-hospital events			
All-cause mortality, n	5 (3.3%)	2 (0.1%)	<0.001
Major adverse cardiovascular events, n	18 (12%)	20 (0.9%)	<0.001
Acute myocardial infarction, n	2 (1.3%)	14 (0.7%)	0.285
Stroke, n	3 (2%)	6 (0.3%)	0.018
Tamponade, n	12 (8%)	0 (0.0%)	<0.001
Major bleeding, n	5 (3.3%)	10 (0.5%)	0.002
Vascular access site complication, n	3 (2%)	24 (1.1%)	0.418
Contrast induced acute kidney injury, n	2 (1.3%)	6 (0.3%)	0.093

Continuous variables are expressed as mean ± SD.

CTO = chronic total occlusion; J-CTO = multicenter CTO Registry of Japan; PROGRESS-CTO = Prospective Global Registry for the Study of Chronic Total Occlusion Intervention.

CLEAN) was then created based on clinical applicability and discriminative capacity with the following 5 variables: previous CABG (1 point), occlusion length (20 to <60 mm, 1 point; ≥60 mm, 2 points), LVEF <50% (1 point), age (50 to <70 years, 1 point; ≥70 years, 2 points), and heavy calcification (1 point).[6] The model was internally validated with bootstrapping. Hirai et al[6] reported that the OPEN-CLEAN perforation score and the corresponding risk of perforation

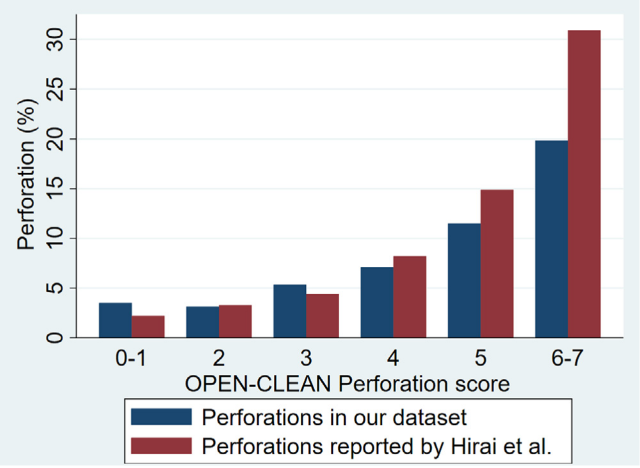

Figure 1. Incidence of coronary artery perforation for each value of the OPEN-CLEAN perforation score.[6]

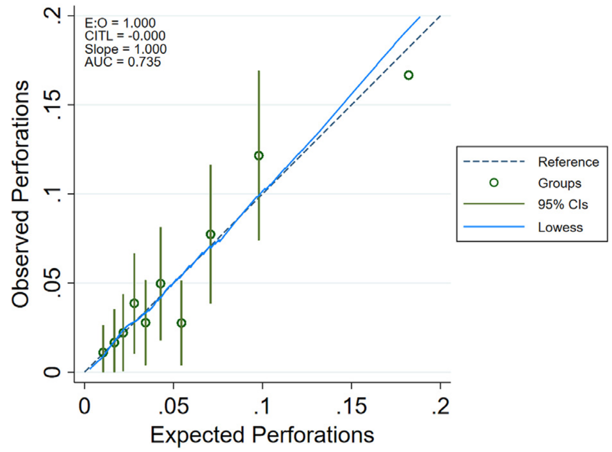

Figure 3. Calibration plot for OPEN-CLEAN perforation score in this independent dataset. CITL = calibration-in-the-large; E = expected; O = observed.

were 2.2% (score 0 to 1), 3.3% (score 2), 4.4% (score 3), 8.2% (score 4), 14.9% (score 5), 30.9% (score 6 to 7).

Here, we externally validated the OPEN-CLEAN perforation model in a larger independent CTO PCI dataset (150 vs 89 perforations) as reported in Hirai et al,[6] and calculated the risk percentages for each corresponding score: 3.5% (score 0 to 1), 3.1% (score 2), 5.3% (score 3), 7.1% (score 4), 11.5% (score 5), 19.8% (score 6 to 7), indicating that except for the maximum values (6 to 7), the similarity between the corresponding risk percentages was excellent (Figure 1). The number of patients in the score 6 to 7 range was limited in the original dataset, which might have contributed to higher point estimates.[6]

Similarly, the performance of the OPEN-CLEAN perforation score was recently assessed in the PROGRESS-CTO (PROspective Global REgiStry for the Study of Chronic Total Occlusion Intervention) (*Clinicaltrials.gov* identifier: NCT02061436), demonstrating an AUC of 0.62 (95% CI 0.59 to 0.65), with higher OPEN-CLEAN score corresponding to a higher risk of perforation.[8] These differences in risk model performance across diverse cohorts reflect differences in practice patterns and baseline risk of the study

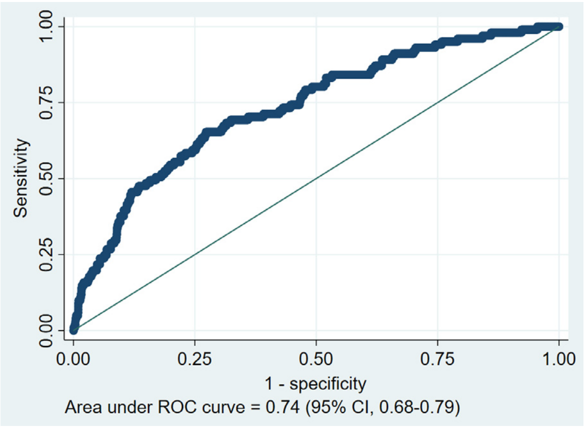

Figure 2. ROC curve for OPEN-CLEAN perforation score in this independent dataset. ROC = receiver operating characteristics

populations and highlight the challenges underlying the quantification of the risk of adverse events in complex procedures such as CTO PCI.

The OPEN-CLEAN perforation score also accurately predicted cardiac tamponade in our dataset (AUC 0.75, 95% CI 0.58 to 0.92). PROGRESS-CTO pericardiocentesis risk score (original dataset AUC 0.78, 95% CI 0.72 to 0.83) is another score in patients without previous CABG based on 83 pericardiocentesis events with age ≥65 years (1 point), female gender (1 point), moderate-severe calcification (1 point), anterograde dissection and re-entry (1 point), or retrograde strategy (2 points) that was created to predict the risk of cardiac tamponade requiring pericardiocentesis in patients who underwent CTO PCI.[9]

CTO PCI has a higher risk of periprocedural complications compared with non-CTO PCI.[10,11] Because of complication risk and equivocal randomized controlled trial evidence for procedural benefit,[12–15] the 2021 American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions guidelines for coronary artery revascularization downgraded the recommendation for CTO PCI to class IIb (level of evidence B): "In patients with suitable anatomy who have refractory angina on medical therapy, after treatment of non−CTO lesions, the benefit of PCI of a CTO to improve symptoms is uncertain." Therefore, more accurate approaches to patient selection, risk/benefit assessment, procedural planning, and readiness for complication management are essential in CTO PCI.[16] The current results further support the OPEN-CLEAN score as a tool to improve risk assessment and guide the risk-to-benefit ratio of CTO PCI for individual patients. The further validation of the OPEN-CLEAN score would be to combine other datasets and compare the perforation rates and the predictive capacity of the OPEN-CLEAN score in different registries across the world with various patient co-morbidities and practice patterns.

Relatively high rate of coronary artery perforation in CTO PCI (5%) highlights the importance of complication prevention and management.[3] Performing dual injection, confirming distal true luminal wire position before advancing microcatheters and balloons, monitoring the distal wire position constantly, and refraining from higher risk strategies, such as crossing of epicardial collaterals as much as possible, continual monitoring of hemodynamics, rapid identification, and treatment of perforation might help minimize the risk of perforation and optimize outcomes.[17−21] Because of the infrequent incidence of perforation in non-PCI (0.7%),[10] it is unlikely that operators will learn and feel comfortable in the management of perforations by performing more PCIs.[22] Participating in complication management courses and simulation training might help prepare interventional cardiologists for complications and optimize outcomes.[22]

The strengths of our study include a larger sample size, inclusion of a more heterogeneous patient population, and wider diversity of practice patterns compared with the original report.[6] Our study also has limitations. First, procedures were performed at dedicated, high-volume CTO PCI centers by experienced operators, which could potentially limit the generalizability of the findings to centers with limited CTO PCI experience. Second, core lab adjudication of the angiograms was not performed, and perforations were self-reported by the operators. Finally, the number of tamponades was small, and additional model validation might be required.

Given the good performance in this independent dataset and the ease of calculation before the procedure, the OPEN-CLEAN perforation score may facilitate risk-benefit assessment before CTO PCI.

Acknowledgment

The authors are grateful for the philanthropic support of our generous anonymous donors and the philanthropic support of Mary Ann and Donald A Sens, Diane and Cline Hickok, Wilma and Dale Johnson, Charlotte and Jerry Golinvaux Family Fund, the Roehl Family Foundation, and the Joseph Durda Foundation. The generous gifts of these donors to the Minneapolis Heart Institute Foundation's Science Center for Coronary Artery Disease (CCAD) helped support this research project.

Disclosures

Dr. Abi Rafeh reports as CTO Proctor and consultant for Boston Scientific and Abbott Vascular. Dr. Alaswad reports as consultant and speaker for Boston Scientific, Abbott cardiovascular, Teleflex, and CSI. Dr. Azzalini reports honoraria from Teleflex, Abiomed, Asahi Intecc, Philips, Abbott Vascular, GE Healthcare, and Cardiovascular System, Inc. Dr. Brilakis reports as consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor Circulation), Amgen, Asahi Intecc, Biotronik, Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), CSI, Elsevier, GE Healthcare, IMDS, Medicure, Medtronic, Siemens, and Teleflex; Research support: Boston Scientific, GE Healthcare; Owner, Hippocrates LLC; Shareholder: MHI Ventures, Cleerly Health, and Stallion Medical. Dr. Choi reports as Medtronic advisory board. Dr. De Oliveria reports research grants from Asahi and Boston Scientific. Dr. Dens reports as consultancy fee from Abbott, Asahi, Boston Scientific, IMDS, Terumo (Canon), and Teleflex. Dr. Doshi reports as speaker's bureau for Abbott Vascular, Boston Scientific, and Medtronic and research support from Biotronik. Dr. ElGuindy reports consulting honoraria: Medtronic, Boston Scientific, Asahi Intecc, and Abbott. Proctorship fees: Medtronic, Boston Scientific, Asahi Intecc, and Terumo. Educational grants: Medtronic. Dr. Grantham reports speaking fees and honoraria from Boston Scientific, Abbott Vascular, and Asahi Intecc and institutional research grant support from Boston Scientific. Part-time employee of Corindus Vascular Robotics and owns equity in the company. Dr. Hirai reports as honoraria from Abiomed. Dr. Jaffer reports as sponsored research: Canon, Siemens, Shockwave, Teleflex, Mercator, Boston Scientific; Consultant: Boston Scientific, Siemens, Magenta Medical, IMDS, Asahi Intecc, Biotronik, Philips, Intravascular Imaging. Equity interest: Intravascular Imaging Inc, DurVena. Massachusetts General Hospital − licensing arrangements: Terumo, Canon, Spectrawave, for which FAJ has right to receive royalties.

Dr. Karmpaliotis reports honoraria Boston Scientific, Abbott Vascular Equity: Saranas, Soundbite, Traverse Vascular, and Nanowear. Dr. Kearney reports as consultant fee/ Honoraria/Speaker's bureau (Personal): Boston Scientific Corporation; Abiomed; Cardiovascular Systems, Inc; Grant Support/Research Contract (Personal)—Teleflex. Dr. Khatri reports as personal honoria for proctoring and speaking: Abbott Vascular, Asahi Intecc, Terumo, Boston Scientific. Dr. Lombardi reports as consultant BSc, Abbott Vascular, Cordis, Teleflex, Asahi Intecc, Medtronic; Royalty Asahi Intecc; Equity, Rampart IC. Dr. Ojeda reports as advisory Board: Edwards Lifesciences, Medtronic Receipt of honoraria or consultation fees: Abbott, Boston Scientific, Philips, World Medical. Dr. Padilla reports as proctor/consulting Boston Scientific, Terumo. Dr. Pan reports lecture frees from Abbott, Boston, Philips, and Asahi. Dr. Rinfret reports as consultant for Boston Scientific, Teleflex, Medtronic, Abbott, and Abiomed. The remaining authors have no conflicts of interest to declare.

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