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# In-stent chronic total occlusion angioplasty in the LATAM-CTO registry

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## Abstract

**Objectives:** To inform about contemporary PCI practice of in-stent (IS) chronic total occlusions (CTO) from a large international registry in Latin America.

**Background:** IS-CTO represent a distinctive challenge for PCI, but literature is limited and restricted to high-resource regions of the world.

**Methods:** Patients undergoing CTO PCI enrolled in the LATAM CTO registry from 42 centers in eight countries were included. We analyzed demographics, angiographic, procedure technique, success and postprocedural outcomes between IS-CTO and non-IS-CTO PCI.

**Results:** From 1,565 patients IS-CTO was present in 181 patients (11.5%). IS-CTO patients had higher prevalence of diabetes and hypertension than patients without IS-CTO. IS-CTOs had less calcification (32.5 vs. 46.7%, $p < .001$), lower prevalence of a proximal branch (36.3 vs. 50.1%, $p < .001$), more likely to be ostial (24.4 vs. 18.1%, $p = .042$), were longer (28.5 vs. 25.2 mm, $p = .062$), and had less interventional collaterals (49.1 vs. 57.3%, $p = .038$) compared with non-IS-CTO. CTO complexity scores were similar between both groups. There was no statistically significant difference in the initial or successful strategy between IS-CTO and non-IS-CTO PCI. Technical success rates remained high in IS-CTO (86.7%) and non-IS-CTO (83.1%, $p = .230$). There was no independent association between IS-CTO and technical success in multivariable analysis. There were no differences between IS-CTO and non-IS-CTO groups for in-hospital clinical outcomes.

**Conclusion:** In a contemporary, multicenter, and international registry from Latin America, IS-CTO PCI is frequent and has comparable technical success and safety profile compared to non-IS-CTO PCI.

KEYWORDS

coronary artery disease, percutaneous coronary intervention, stent restenosis

## 1 | INTRODUCTION

Patients with in-stent (IS) chronic total occlusions (CTO) represent a distinctive challenge for percutaneous coronary interventions (PCI).[1] Pathophysiology and techniques differ from native vessel nonstented CTO.[2,3] The existing literature is quite limited and inconclusive in terms of prevalence, approach used, success rates, and subsequent outcomes when compared to nonstented CTO PCI.[4-7] Most of the information available comes from North America and Europe, leaving other regions underrepresented.

The LATAM CTO PCI registry has recently been implemented to collect data of contemporary CTO PCI performed in 42 centers in eight Latin American countries. The goal of this registry is to better understand the status and progress of CTO PCI in this region. Beyond its valuable regional aspect, the aim of this analysis is to better inform about contemporary practice and status of PCI involving IS-CTO.

## 2 | MATERIAL AND METHODS

### 2.1 | Population

The Brazilian Society of Interventional Cardiology created and coordinated an ongoing international registry of CTO PCI: the LATAM CTO registry. Centers in Latin America were invited and/or volunteered to participate. There was no specific requirement regarding CTO PCI volume for center participation. Patients over 18 years old undergoing a CTO PCI attempt were considered eligible.

### 2.2 | Data collection

Investigators added CTO PCI data in an online platform coordinated by the Brazilian Society of Interventional Cardiology and managed by the Instituto de Cardiologia do Rio Grande do Sul, Brazil. Access to the database was available via research electronic data capture (REDCap), a secure and free-access web application developed by the Vanderbilt University that meets international standards and requirements from the Brazilian National Agency for Sanitary Surveillance.[8] All investigators received standardized instructions for data entry in REDCap, and clinical, procedural, angiographic information, and post-procedural clinical outcomes were collected in the same platform.

### 2.3 | Definitions

The definition of a CTO was as a 100% occlusion in a major coronary artery present for at least 3 months. IS-CTO PCI was defined as a PCI attempt in a coronary segment with prior metallic stent(s) and occlusive stenosis 5 mm proximal or within the stent. Clinical, angiographic, procedural, and postprocedure outcomes used standard definitions from the LATAM CTO registry.[9] In-hospital major adverse cardiovascular events (MACE) was defined as all-cause death, myocardial infarction, or stroke. Myocardial infarction was defined using the universal definition of MI (type 4a MI) (22). Stroke was defined as a new focal neurological deficit of sudden onset of presumably cerebrovascular irreversible cause (or resulting in death) within 24 hr and not caused by any other easily identifiable cause.

### 2.4 | Statistical analysis

We describe demographic, angiographic, and procedural characteristics as percentages or mean with standard deviation, as appropriate. Categorical variables were analyzed using $Chi^2$ and continuous variables using T test. The impact of IS-CTO on success rates was analyzed with multivariable logistic regression including different validated success scores including J-CTO, PROGRESS, ORA, and CL-SCORE.

Ethic approval was obtained in each participating center and participants provided consent for their data to be collected for research purposes. The authors are solely responsible for the design and conduct of the study, statistical analysis, drafting and editing of the paper, and approval of its final contents. The study was funded by educational grants from the Brazilian Society of Interventional Cardiology and Boston Scientific.

## 3 | RESULTS

### 3.1 | Population

From January 2013 to October 2019; 1,618 CTO PCIs were enrolled in the LATAM registry. In this analysis we included 1,565 (96.7%) with available data on the presence of an occluded stent within the treated CTO segment. IS-CTO was present in 181 patients (11.5%). Most of demographic variables were similar between IS-CTO and non-IS-CTO patients, except for the prevalence of diabetes and hypertension, which were higher in IS-CTO patients (Table 1).

### 3.2 | Angiographic characteristics

Patients with IS-CTO were less likely to have three-vessel disease compared to the non-IS-CTO group (15.1 vs. 22.9%, $p = .018$) with no differences in CTO location ($p = .42$, Table 2). While most of the angiographic variables associated with CTO PCI success were balanced, IS-CTOs featured some anatomical peculiarities. IS-CTOs had less calcification (32.5 vs. 46.7%, $p < .001$), lower prevalence of a proximal branch (36.3 vs. 50.1%, $p < .001$), more likely to be ostial (24.4 vs. 18.1%, $p = .042$), longer (28.5 vs. 25.2 mm, $p = .062$), and had less interventional collaterals (49.1 vs. 57.3%, $p = .038$) compared to non-IS-CTO. CTO complexity scores were similar between both groups (Figure 1).

### 3.3 | CTO intervention

There was no statistically difference in initial or successful strategy between IS-CTO and non-IS-CTO PCI (Figure 2). Technical success

**TABLE 1** Patient characteristics

| | Overall (*n* = 1,565) | IS-CTO (*n* = 181) | Non-IS-CTO (*n* = 1,384) | *p*-value |
|---|---|---|---|---|
| Female sex, % (n/N) | 21.6 (339/1565) | 22 (40/181) | 21.6 (299/1384) | .879 |
| Age, mean (*SD*) | 64.1 (10.5) | 65.1 (10.6) | 63.9 (10.5) | .719 |
| White race, % (n/N) | 35.1 (527/1490) | 35.4 (62/175) | 35.1 (462/1315) | .938 |
| Diabetes, % (n/N) | 36.3 (564/1551) | 44.4 (80/180) | 35.3 (484/1371) | .016 |
| Hyperlipidemia, % (n/N) | 71.2 (1,104/1550) | 75.5 (136/180) | 70.6 (968/1370) | .172 |
| Hypertension, % (n/N) | 88.0 (1,366/1551) | 92.7 (167/180) | 87.4 (1,199/1371) | .038 |
| Family history, % (n/N) | 27.4 (418/1522) | 33.1 (58/175) | 26.7 (360/1347) | .073 |
| Smoking, % (n/N) | 17.9 (277/1545) | 19.1 (34/178) | 17.7 (243/1367) | .664 |
| Obesity, % (n/N) | 27.3 (373/1365) | 26.5 (43/162) | 27.4 (330/1203) | .811 |
| Prior PCI, % (n/N) | 49.1 (704/1433) | 100 (177/177) | 42.9 (539/1256) | <.001 |
| Prior CABG, % (n/N) | 15.5 (223/1435) | 16.3 (29/177) | 15.4 (194/1258) | .740 |
| Prior stroke, % (n/N) | 3.6 (53/1433) | 3.9 (7/177) | 3.6 (46/1256) | .846 |
| Peripheral arterial disease, % (n/N) | 8.5 (122/1432) | 9.6 (17/176) | 8.3 (105/1256) | .563 |
| Prior MI, % (n/N) | 40.7 (583/1431) | 46.5 (82/176) | 39.9 (501/1255) | .091 |
| Heart failure, % (n/N) | 10.6 (153/1432) | 9.0 (16/177) | 10.9 (137/1255) | .449 |
| Creatinine clearance <30 ml/min, % (n/N) | 7.8 (113/1432) | 9.6 (17/176) | 7.6 (96/1256) | .352 |

Abbreviations: CABG, coronary artery bypass surgery; MI, myocardial infarction; PCI, percutaneous coronary intervention.

rates remained high in both IS-CTO (86.7%) and non-IS-CTO (83.1%, $p = .230$). There was no independent association between IS-CTO and technical success in multivariable analysis accounting for the different complexity scores (Figure 3), and there were also no differences in crossing time (mean, 30.3 vs. 34.4 min in non-IS-CTO PCI, $p = .285$), fluoroscopy time (mean, 40.5 vs. 41.8 min in non-IS-CTO PCI, $p = 0.927$), or radiation dose in IS-CTO PCI (median, air Kerma 2,546 mGray vs. 2,150 mGray in non-IS-CTO PCI, $p = .201$).

CrossBoss® was more frequently used in IS-CTO PCI compared to non-IS-CTO PCI (15.8 vs. 3.1%, $p < .001$) and in more complex lesions (ORA score: 6.27 vs. 2.4, $p < .001$, respectively). The use of CrossBoss® was not associated with improved technical success (OR 0.77, 95% CI 0.23–2.54, $p = .66$) and although crossing time was numerically shorter (43.4 vs. 30.2 min, $p = .96$) in IS-CTO PCI patients this difference was not statistically significant.

### 3.4 | Procedural safety

There were no differences between groups in periprocedural outcomes, including cardiac tamponade, heart failure, shock, bleeding, mortality, revascularization, or stroke (Table 3).

## 4 | DISCUSSION

In this contemporary, multicenter and international registry, IS-CTO PCI was relatively common. The IS occlusions displayed specific angiographic characteristics that contrasted from non-IS-CTO lesions. We observed comparable technical success, procedural strategies, and complication rates between IS-CTO PCI and non-IS-CTO PCI. We could not demonstrate an independent association between IS-CTO and technical success. Despite more frequent use of CrossBoss® in patients with IS-CTO than non-IS-CTO, device utilization was lower when compared to other developed regions.[6]

We believe our results are relevant because literature related to IS-CTO is scarce (with total of less than 1,000 procedures for comparative analysis), making our study one of the largest analytical report of IS-CTO PCI to date. In those studies the prevalence of IS-CTO PCI ranged from 10 to 25%,[4,10] which is similar to what we report in our study (11.5%). The higher prevalence of IS-CTO in diabetics patients may be related to higher restenosis rates in this population, however this is not fully consistent with prior literature.[6] The association of hypertension with IS-CTO was markedly attenuated after exploratory statistical adjustment by diabetic status, suggesting a confounding association.

Angiographic characteristics were similar between both groups however; there were a few key differences. The lower prevalence of calcification observed in IS-CTOs may be related to the pathophysiology of these lesions. Neointimal hyperplasia with subsequent complete luminal loss, represents a common mechanism for this specific type of stent failure.[6] Patients with recently occluded stent(s) may recognize symptoms faster than those without previous history of revascularization and hence the lesion be treated during the neointimal phase of restenosis. Another explanation could be poor visualization of calcium through the stent frame, this is especially true for long-standing occlusions, given its well-known association with high calcium and fibrosis burden (neo-atherosclerosis).

**TABLE 2** Angiographic characteristics

| | IS-CTO | Non-IS-CTO | *p*-value |
|---|---|---|---|
| Stump, % (n/N) | 49.7 (89/179) | 45.7 (623/1361) | .319 |
| Severe calcification, % (n/N) | 32.5 (58/178) | 46.7 (638/1365) | < .001 |
| Angulation, % (n/N) | 3.3 (6/179) | 4.3 (59/1365) | .543 |
| Prior attempt, % (n/N) | 17.2 (31/180) | 12.9 (179/1377) | .118 |
| Ambiguity, % (n/N) | 26.1 (47/180) | 31.7 (435/1369) | .122 |
| Proximal tortuosity, % (n/N) | 5.5 (10/180) | 5.1 (70/1367) | .804 |
| Absence of interventional collaterals, % (n/N) | 49.1 (88/179) | 57.3 (786/1371) | .038 |
| Ostial, % (n/N) | 24.4 (44/180) | 18.1 (249/1372) | .042 |
| Proximal branch, % (n/N) | 36.3 (65/179) | 50.1 (686/1368) | < .001 |
| Bifurcation, % (n/N) | 38 (62/163) | 31.4 (406/1290) | .091 |
| Left main, % (n/N) | 7.7 (14/180) | 7 (97/1374) | .725 |
| 3-vessel disease, % (n/N) | 15.1 (27/178) | 22.9 (316/1377) | .018 |
| Length, mm (mean (SD)) | 28.5 (16.1) | 25.2 (15.4) | .062 |
| Location, % (n/N) | | | .415 |
| Left main | 0 (0/179) | 0.7 (10/1372) | |
| LAD | 38.5 (69/179) | 33.6 (462/1372) | |
| LCX | 22.3 (40/179) | 23.3 (320/1372) | |
| RCA | 39.1 (70/179) | 42.2 (580/1372) | |

Abbreviations: LAD, left-anterior descendent artery; LCX, left circumflex artery; RCA, right coronary artery.

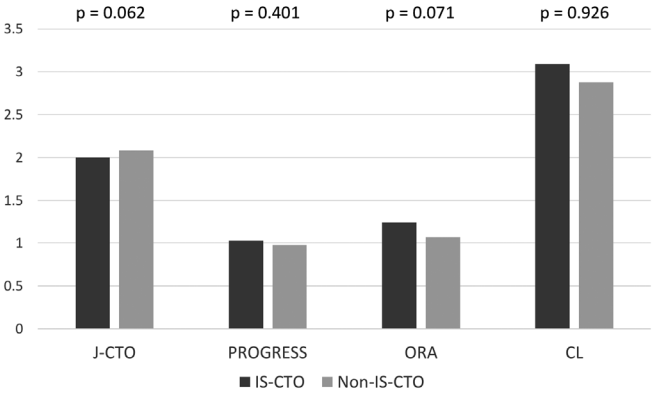


**FIGURE 1** Angiographic success scores and status of IS-CTO. Patients with IS-CTO had similar success scores than those with non-IS-CTO. IS-CTO: In-stent chronic total occlusion

The lower prevalence of proximal side branches in the IS-CTO group maybe partially explained by the morphology and geographic location of the occlusive segment. Stent restenosis are more likely to have a proximal cap within the stent frame, which is usually away from major side branches. IS-CTOs were longer than non-IS-CTOs, which is also aligned with prior literature regarding stent length and TLR.[6] Ostial location was more frequent in IS-CTOs and although consistent with prior reports, its explanation is less clear.[6] This may be related to more frequent ostial location of stents to cover original lesions (which operators usually avoid leaving a small gap and prefer to cover the ostium) versus de novo stenoses which follow a more random distribution. Finally, IS-CTOs were less likely to have interventional collaterals. The fact that IS-CTO lesions are longer and may be jailing several side branches, may imply less available tributaries that although, receiving collaterals flow, might be perceived as not amenable for intervention. By the same principle, if the available collateral channels connect at the terminal portion of the vessel, as usually happens with epicardial collaterals, these may also be perceived as non-interventional by less experienced operators.

Despite the previously reported characteristics that are predictive of CTO PCI success in IS-CTO and non-IS-CTOs recanalization attempts, the four success scores tested in this analysis (J-CTO, PROGRESS, ORA, and CL) were not statistically different between groups. To our understanding, calculation of these scores in IS-CTO PCI were not adequately or dedicatedly validated in prior studies. Finding mismatch (imbalance of some known predictors of angiographic predictors of CTO PCI but similar scores) raises concern for possible lower prediction properties of these scores in IS-CTO PCI. Although this report is one of the largest analytical (including both IS-CTOs and non-IS-CTOs) study published to date, statistical power limits its ability to properly test the prediction performance of these scores in IS-CTO PCI. More research is required to achieve proper conclusions about this potential issue.

Both the initial and successful strategies were similar between IS-CTOs and non-IS-CTOs. Compared to other reports, the use of device based antegrade dissection and re-entry (ADR) technique was infrequent in our cohort.[6] This may be partially explained by lower availability of dedicated ADR equipment and hence lower number of trained operators in Latin America. It is important to state that the few ADR cases in the IS-CTO group are unlikely to represent a subadventitial stent-crush technique, but rather the use of this strategy to re-enter into the true lumen after exiting the occluded stent in subadventitial fashion.[11]

Technical success rates remained high in IS-CTOs, which is aligned with other recent reports.[6,7] IS-CTO did not predict technical success in univariable or multivariable models. Although there is a lack of prior analyses using multivariable adjustment to test the predictability of IS-CTO for technical success, univariable analysis from recent studies are similar to our findings.[6] We observed no important differences in fluoroscopy and crossing times, or radiation dose.

Compared to recent registries in developed countries, the use of CrossBoss® in IS-CTO PCI was markedly lower in our region.[6] The concept behind its adoption in IS-CTO is that the presence of stent struts within the occlusive segment prevents device exit to the subadventitial space or side-branch facilitated by the device's 1 mm blunt atraumatic tip and the use of the "fast-spin technique."[12] The use of CrossBoss® in IS-CTO PCI was associated with shorter crossing time in a prior randomized clinical trial.[13] We could not find a statistically significant difference between CrossBoss® and shorter crossing time or technical success. This is probably due to lack of statistical power in the small subset of participants where CrossBoss® was used.

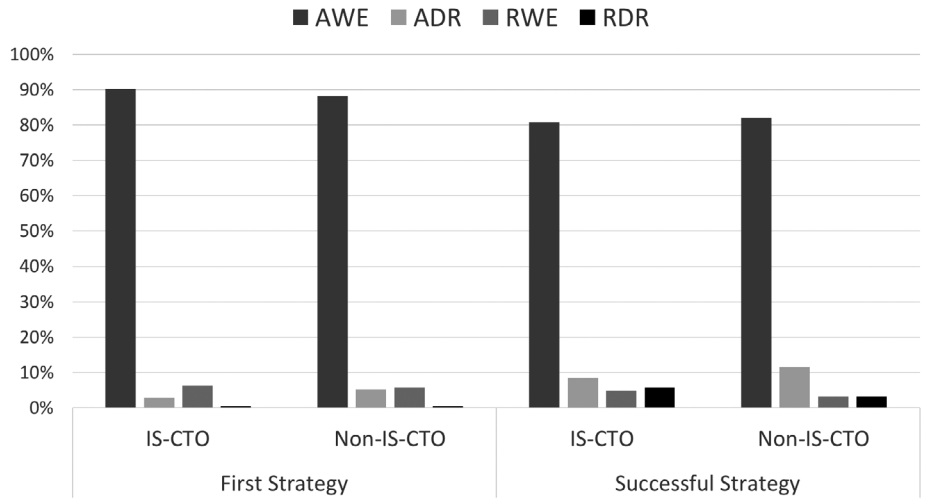


**FIGURE 2** First and successful strategies by IS-CTO status. Initial or final successful strategies were similar between both groups. AWE, antegrade wire escalation; ADR, antegrade dissection re-entry; IS-CTO, in-stent chronic total occlusion; RWE: retrograde wire escalation; RDR, Retrograde dissection re-entry

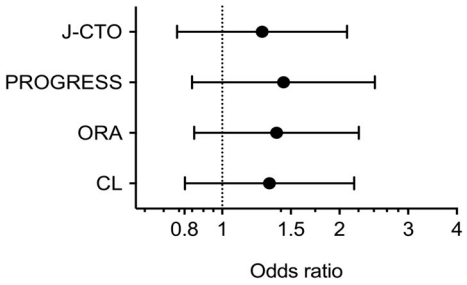


**FIGURE 3** Association between IS-CTO and success adjusted by different complexity scores. IS-CTO was not associated with technical success when adjusted by different angiographic complexity scores

**TABLE 3** In-hospital clinical outcomes

| | IS-CTO | Non-IS-CTO | *p*-value |
|---|---|---|---|
| Cardiac tamponade, % (n/N) | 0 (0/180) | 0.8 (14/1383) | .063 |
| Heart failure, % (n/N) | 0.5 (1/180) | 1.5 (24/1383) | .177 |
| Retroperitoneal bleeding, % (n/N) | 0 (0/180) | 0.5 (8/1383) | .161 |
| Any bleeding, % (n/N) | 1.1 (2/180) | 3 (46/1383) | .067 |
| Cardiogenic shock, % (n/N) | 0.5 (1/179) | 1.2 (19/1383) | .310 |
| Mortality, % (n/N) | 1.7 (3/175) | 1.4 (19/1301) | .798 |
| Stroke, % (n/N) | 1.1 (2/176) | 0.4 (4/1299) | .168 |
| MI, % (n/N) | 1.1 (2/172) | 1.3 (18/1294) | .804 |
| CABG, % (n/N) | 0 (0/175) | 0.2 (3/1300) | .383 |
| TLR, % (n/N) | 0.5 (1/175) | 1 (15/1295) | .445 |
| MACE-R, % (n/N) | 4.5 (8/174) | 4 (51/1294) | .684 |
| MACE-R + T, % (n/N) | 4.6 (8/173) | 4.9 (63/1259) | .890 |
| MACE, % (n/N) | 4 (7/174) | 2.9 (37/1299) | .412 |

Abbreviations: CABG, Coronary artery bypass surgery; IS-CTO, In-stent chronic total occlusion; MACE, Major-adverse coronary events; MACE-R, Major-adverse coronary events with any revascularization; MACE-R+T, Major-adverse coronary events with any revascularization and tamponade; MI, Myocardial infarction; TLR, Target-lesion revascularization.

Another possible explanation could be that its use was prioritized for more complex anatomies given its availability, cost, and lack of improved success rates on published data.[13] In our study the use of CrossBoss® in IS-CTOs was indeed associated with more complex anatomies based on complexity scores (see CTO Intervention section).

We did not find significant differences regarding in-hospital procedural safety outcomes between patients with or without an IS-CTO recanalization attempt, which is consistent with prior reports.[4] Cohorts with follow-up after discharge found increased target vessel revascularization among IS-CTO PCI patients, but with no difference in other major outcomes.[6]

## 4.1 | Limitations

There are limitations worth commenting. This is an analysis from CTO PCIs done in Latin America, despite being an international and multicenter registry, these results are derived from all levels of expertise ("real world"). Then, it may not apply to other regions with more equipment availability or compare with results obtained from other registries with "expert only" participation, in which lesion complexity is usually less favorable. With that said, it still provides valuable information regarding geographic tendencies and insides regarding recanalization of IS-CTO lesions. The registry is not core-lab adjudicated. All angiographic characteristics are site-reported and differences in angiographic appraisal between centers or even members may be present. Is important to mention that only one of the large CTO PCI registries uses an angiographic core-lab.[14] Nonetheless, to minimize such variability, all centers received data-collection training, including the definition of each variable collected, and we periodically checked the database for outliers, spurious values, and asymmetries in an effort to improve data quality. The outcomes were also site-reported with potential under-reporting, a shared limitation to other nonaudited registries in the world.[15,16] In the present report we did not assess long-term outcomes, and we plan to report these in future analysis.

## 5 | CONCLUSIONS

In a contemporary, multicenter and international registry from Latin America, IS-CTO PCI is relatively frequent and with comparable technical success and safety profile compared with non-IS-CTO PCI. Our results are can be used in clinical practice when discussing associated risks and chances of success of IS-CTO PCI with patients and clinical cardiologists. Future analysis including long-term data will better inform about durability of this procedure.


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### CONFLICT OF INTEREST

None of the authors has conflicts of interests for the manuscript subject submitted.


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