Clinical Investigation

Percutaneous Coronary Intervention to Treat Chronic Total Occlusion:

Predictors of Technical Success and One-Year Clinical Outcome

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We investigated the overall success rate of percutaneous coronary intervention (PCI) as a treatment for coronary chronic total occlusion and sought to determine the predictive factors of technical success and of one-year major adverse cardiac events (MACE). These factors have not been conclusively defined.

Using data from our single-center PCI registry, we enrolled 269 consecutive patients (mean age, 56.13 ± 10.72 yr; 66.2% men) who underwent first-time PCI for chronic total occlusion (duration, ≥3 mo) from March 2006 through September 2010. We divided them into 2 groups: procedural success and procedural failure. We compared occurrences of in-hospital sequelae and one-year MACE between the groups, using multivariate models to determine predictors of technical failure and one-year clinical outcome.

Successful revascularization was achieved in 221 patients (82.2%). One-year MACE occurred in 13 patients (4.8%), with a predominance of target-vessel revascularization (3.7%). The prevalence of MACE was significantly lower in the procedural-success group (1.8% vs 18.8%; P <0.001). In the multivariate model, technical failure was the only predictor of one-year MACE. The predictors of failed procedures were lesion location, multivessel disease, the occurrence of dissection, a Thrombolysis In Myocardial Infarction flow grade of 0 before PCI, the absence of tapered-stump arterial structure, and an increase in serum creatinine level or lesion length.

In our retrospective, observational study, PCI was successful in a high percentage of chronic total occlusion patients and had a low prevalence of complications. This suggests its safety and effectiveness as a therapeutic option. ***(Tex Heart Inst J 2014;41(1):40-7)***

Key words: *Angioplasty, balloon, coronary/methods; chronic disease/therapy; coronary occlusion/therapy; disease-free survival; heart diseases/prevention & control; multivariate analysis; myocardial revascularization; patient selection; retrospective studies; treatment outcome*

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As a treatment for coronary chronic total occlusion (CTO), percutaneous coronary intervention (PCI) is widely considered to be one of the most complex procedures in interventional cardiology. The low overall success rate of PCI is predominantly attributable to an inability to cross occlusions with an interventional guidewire.[1-5] The overall prevalence of CTO on diagnostic angiograms is 15% to 30%. The results of recent studies show that one third to one half of patients with angiographically significant coronary artery disease have at least one CTO.[6-8] On the basis of the available data, PCI is performed in only 10% to 15% of CTO angioplasty procedures[2]—most patients with CTO are referred for coronary artery bypass grafting (CABG) or are prescribed medical therapy.

New techniques and dedicated devices and improved operator experience have markedly increased the procedural success rate for occlusion recanalization. Investigators conducting large studies in different settings have reported short- and long-term survival advantages associated with successful PCI of chronic occlusions in comparison with failed procedures and have tried to identify clinical and procedural predictors of the success and outcome of PCI.[1,9-12] However, debate continues in regard to whether the benefits of occlusion recanalization outweigh the risks and challenges. The specific factors that might enable the best choice of treatment for patients with CTO (PCI vs CABG or medical therapy) have not been conclusively identified.[3,8,11]

In the present retrospective study, we investigated the overall success rate of PCI in CTO patients. We sought to determine the in-hospital and one-year outcomes of patients undergoing the procedure, and identify factors that adversely influence the success rate of PCI and the occurrence of one-year major adverse cardiac events (MACE).

Patients and Methods

We extracted our data from the Tehran Heart Center Registry of Interventional Cardiology, a single-center registry in which all adult patients who undergo PCI are enrolled without any specific exclusionary criteria. Detailed data on demographic and clinical characteristics, procedures, complications, and clinical outcomes are documented in the registry. As a routine practice, follow-up data are obtained from all patients upon their discharge from the hospital, and then 1, 6, and 12 months after PCI during organized clinical visits or through telephone contact by trained research physicians and nurses.

Study Population

We identified all patients with CTO of a coronary artery (duration, ≥3 mo) who underwent first-time PCI at Tehran Heart Center from March 2006 through September 2010. Chronic occlusions of bypassed vessels, patients treated solely by means of plain old balloon angioplasty, and occlusions of estimated durations shorter than 3 months were excluded. Of 283 patients who met the inclusionary criteria, 14 had been lost to follow-up and were excluded from analysis; complete follow-up was achieved in 269 (95.05%) of the patients. We enrolled these 269 consecutive patients (mean age, 56.13 ± 10.72 yr; 66.2% men) into either of 2 groups on the basis of procedural success or failure. The protocol for this retrospective, observational study was approved by our institutional review board.

Definitions

Chronic total occlusion was defined as vessel continuity completely interrupted by an atherosclerotic lesion in a native coronary artery, with a Thrombolysis In Myocardial Infarction (TIMI) flow grade of 0 or 1 for 3 months or longer; or as the presence of bridging collateral vessels.[13] The duration of occlusion was estimated by clinical events such as myocardial infarction (MI) or the sudden onset or worsening of ischemic symptoms, or it was proved by the patients' previous angiographic reports and the presence of bridging collateral vessels on angiograms. Technical success was defined as the ability to cross an occluded segment and successfully open the artery (restoration of a TIMI flow grade of 2 or 3) with a residual stenosis of less than 30% in all views.[14,15]

Multivessel disease was defined as stenosis of ≥70% in more than one major coronary artery. Lesions distal to 2 bends of >75° were considered to have moderate-to-severe tortuosity. Moderate-to-severe calcification was defined as readily apparent densities within the vascular wall at the site of the stenosis. The angiographic structure of the occlusion was defined as "tapered-stump" if the artery ended in a funnel shape. Intracoronary microchannels at the site of the occlusion were considered to be bridging collateral vessels that established the chronicity of the occlusion.[16] Contralateral injection, performed in some cases, was defined as simultaneous dye injection to show the distal portion of the vessel after the occlusion site (filled via collateral vessels) and to estimate the length of the occlusion.[17]

Postprocedural MI was defined as an elevation of creatine kinase-MB mass to at least 3 times the upper limit of normal after the procedure (our laboratory's normal limit of creatine kinase-MB is 6.73 ng/mL for men and 3.77 ng/mL for women). In patients who had a postprocedural MI that was related to the target lesion, the development of new Q waves in the electrocardiographic leads indicated a Q-wave MI.[18]

The study endpoint was the occurrence of MACE during the follow-up period: cardiac death, nonfatal MI, target-lesion revascularization, or target-vessel revascularization (TVR). Target-lesion revascularization was defined either as repeat percutaneous or surgical revascularization for a lesion anywhere within the stent or within 5-mm borders proximal or distal to the stent. Target-vessel revascularization was defined as PCI or CABG for chest pain or positive noninvasive-test results (exercise stress test, stress echocardiogram, or radionuclide study showing reversible defects) for ischemia consequent to a lesion in the same epicardial vessel.

Evaluation Protocol

One independent reviewer retrospectively evaluated all angiograms and angioplasty films, and all reported data arose from that reviewer's decisions. A different independent reviewer reviewed the images from a randomly selected 15% of the patients. The level of agreement between the reviewers was 93.5%. In the evaluation of bridging collateral vessels and moderate-to-severe calcification, interobserver variability was 6.5% and 3.2%, respectively.

Interventional Procedure

Before PCI, all patients were given aspirin orally (325 mg), a clopidogrel loading dose (600 mg, at least 2 hr before), and weight-adjusted unfractionated heparin (80–100 U/kg) intravenously. The technical approach and procedural devices were chosen by the interventional cardiologists. The antegrade approach was routinely used, and, depending on procedural progress, different strategies and the use of stiffer wires were considered. Contralateral injection was performed in some patients.

In the successful-procedure group, clopidogrel (75 mg/d) was prescribed for 12 months to patients who received a drug-eluting stent (DES) and for at least 3 months to patients who received a bare-metal stent (BMS). The patients with a DES were discharged from the hospital with instructions to take 325 mg/d of aspirin for at least 3 months; the patients with a BMS were instructed to take that dose of aspirin for at least 1

month. Thereafter, 80 mg/d of aspirin was prescribed for an indefinite period after PCI.

Statistical Analysis

Results are presented as mean ± SD for numerical variables and as number and percentage for categorical variables. The Student *t* or Mann-Whitney U test was used to compare continuous variables, and the χ^2 or Fisher exact test was used to compare categorical variables. For one-year MACE-free outcome, survival curves were estimated by means of the Kaplan-Meier method (the standard estimator of the survival function) and were compared between the 2 groups by means of the log-rank test.

Variables with a univariate *P* value <0.15 were candidates for inclusion in the multivariate analyses. We constructed a multivariate Cox proportional hazards model with a backward elimination method for identifying variables associated with one-year MACE-free survival outcome. Associations are expressed as hazard ratio (HR) with 95% confidence interval (CI). The overall fit of the final model was checked with use of Cox-Snell residuals, and checks were performed to identify departures from proportional-hazard assumption.

We established a multivariate backward logistic regression model for factors predicting procedural failure. Associations between the independent predictors and procedural failure in the final model are expressed as odds ratio (OR) with 95% CI. We used the area under the receiver operating characteristic curve to measure model discrimination and used the Hosmer-Lemeshow goodness-of-fit statistic to estimate model calibration (higher *P* values imply that the model better fits the observed data). *P* values ≤0.05 were considered statistically significant. We used SPSS software version 15.0 for Windows (IBM Corporation; Armonk, NY) for the statistical analyses.

Results

Table I shows the baseline demographic and clinical characteristics of the study population. Revascularization was successful in 221 of the 269 patients (82.2%). Almost half the patients had hypertension (46.8%), and 73.6% had hyperlipidemia. The only significant difference between the groups in baseline characteristics was the prevalence of multivessel disease, which was significantly higher in the procedural-failure group (64.6% vs 51.1%, *P*=0.049).

Angiographic and Procedural Characteristics

Table II shows the angiographic and procedural characteristics. In 63.2% of the patients, the left anterior descending coronary artery was the chronically occluded target vessel. The procedures performed on lesions with tapered stumps were significantly more successful than those on lesions that lacked that tapered structure. The presence of at least one side branch arising at the site of the occlusion, the finding of moderate-to-severe calcification, and the need for contralateral injection were significantly higher in the procedural-failure group. Most patients in the failure group presented with a TIMI flow grade of 0 before PCI (*P*=0.003). A DES

TABLE I. Baseline Demographic and Clinical Characteristics of the Patients

Variable	**Total** (N=269)	**Procedural Success** (n=221)	**Procedural Failure** (n=48)	***P* Value**
Demographic factors				
Age (yr)	56.13 ± 10.72	55.61 ± 10.46	58.83 ± 11.07	0.059
Male	178 (66.2)	146 (66.1)	32 (66.7)	0.936
Risk factors				
Diabetes mellitus	70 (26)	58 (26.2)	12 (25)	0.859
Hypertension	126 (46.8)	100 (45.2)	26 (54.2)	0.262
Hyperlipidemia	198 (73.6)	161 (72.9)	37 (77.1)	0.546
Current smoking	52 (19.3)	40 (18.1)	12 (25)	0.273
Serum creatinine (mg/dL)	1.1 ± 0.32	1.08 ± 0.26	1.2 ± 0.5	0.125
Renal failure*	5 (1.9)	3 (1.4)	2 (4.2)	0.072
Cardiac history				
Prior STEMI	95 (35.3)	77 (34.8)	18 (37.5)	0.727
No. diseased vessels	—	—	—	0.049
1	125 (46.5)	108 (48.9)	17 (35.4)	—
2	101 (37.5)	83 (37.6)	18 (37.5)	—
3	43 (16)	30 (13.6)	13 (27.1)	—
LV ejection fraction	0.494 ± 0.104	0.498 ± 0.104	0.474 ± 0.107	0.531

LV = left ventricular; STEMI = ST-elevation myocardial infarction

*Defined as baseline creatinine level >2 mg/dL.

Data are presented as mean ± SD or as number and percentage. *P* ≤0.05 was considered statistically significant.

TABLE II. Angiographic and Procedural Characteristics

Variable	Total (N=269)	Procedural Success (n=221)	Procedural Failure (n=48)	*P* Value
Target vessel	—	—	—	0.902
LAD	170 (63.2)	141 (63.8)	29 (60.4)	—
Right coronary artery	72 (26.8)	58 (26.2)	14 (29.2)	—
LCx	27 (10)	22 (10)	5 (10.4)	—
Lesion location	—	—	—	0.089
Ostial	12 (4.5)	7 (3.2)	5 (10.4)	—
Proximal	82 (30.5)	70 (31.7)	12 (25)	—
Mid portion	165 (61.3)	137 (62)	28 (58.3)	—
Distal	10 (3.7)	7 (3.2)	3 (6.3)	—
Lesion length	30.82 ± 13.64	31.51 ± 13.88	27.5 ± 11.96	0.05
Side branch	159 (59.1)	123 (55.7)	36 (75)	0.013
Bridging collateral vessels	10 (3.7)	10 (4.5)	0	0.213
Tapered stump	174 (64.7)	153 (69.2)	21 (43.8)	0.001
Vessel tortuosity	9 (3.3)	7 (3.2)	2 (4.2)	0.664
Moderate-to-severe calcification	29 (10.8)	20 (9)	9 (18.8)	0.05
TIMI flow grade before PCI	—	—	—	0.003
0	161 (59.9)	123 (55.7)	38 (79.2)	—
1	108 (40.1)	98 (44.3)	10 (20.8)	—
Contralateral injection	24 (8.9)	14 (6.3)	10 (20.8)	0.004
Type of PCI	—	—	—	<0.001
Bare-metal stent	45 (16.7)	45 (20.4)	0	—
Drug-eluting stent	178 (66.2)	176 (79.6)	2 (4.2)	—
Guiding catheter type	—	—	—	0.889
Extra support	92 (34.2)	76 (34.4)	16 (33.3)	—
Judkins	177 (65.8)	145 (65.6)	32 (66.7)	—
Guiding catheter size	—	—	—	0.92
6F	181 (67.3)	149 (67.4)	32 (66.7)	—
7F	88 (32.7)	72 (32.6)	16 (33.3)	—
Guidewires	—	—	—	0.515
Hydrophilic	112 (41.6)	90 (40.7)	22 (45.8)	—
Nonhydrophilic	157 (58.4)	131 (59.3)	26 (54.2)	—

LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; PCI = percutaneous coronary intervention; TIMI = Thrombolysis In Myocardial Infarction

Data are presented as mean ± SD or as number and percentage. $P \leq 0.05$ was considered statistically significant.

was deployed in 178 patients (66.2%) and a BMS in 45 patients (16.7%).

According to the multivariate analysis, independent predictors of technical failure were the location of the lesion, 3-vessel coronary artery disease, the absence of tapered-stump morphology, a TIMI flow grade of 0 before PCI, the occurrence of dissection, and an increase in serum creatinine level or lesion length. As Table III shows, PCI for ostial lesions was the most powerful predictor of technical failure (OR=6.77; 95% CI, 1.5–30.58; P=0.013). The area under the receiver operating characteristic curve was 0.761 (95% CI, 0.688–0.834; P <0.001), implying the model's ability to discriminate between failed and successful procedures.

Procedural and In-Hospital Complications

Technical success was achieved in 82.2% of the patients; inability to pass the guidewire was the reason for technical failure. Table IV shows the in-hospital and one-year complications. In 11 patients with coronary artery dissection, 2 had a non-Q-wave MI and one had a Q-wave MI. Mild or minimal pericardial effusion developed in 2 patients without progressing to cardiac tamponade. There were no relevant clinical sequelae in the remaining patients in whom coronary dissection or arterial perforation occurred. In 3 patients who developed postprocedural MI, new Q waves were detected in the electrocardiographic leads related to the target lesion. No emergent CABG was required and no deaths

TABLE III. Multivariate Predictors of Technical Failure*

Variable	Odds Ratio	95% Confidence Interval	*P* Value
Lesion Location			
Proximal	Ref	—	0.054
Mid portion	1.55	0.68–3.54	0.297
Distal	4.15	0.79–21.8	0.092
Ostial	6.77	1.5–30.58	0.013
Tapered-stump morphology	0.35	0.17–0.73	0.005
No. diseased vessels			
1	Ref	—	0.017
2	1.31	0.59–2.87	0.506
3	3.92	1.51–10.18	0.005
TIMI flow grade 1 before PCI	0.31	0.14–0.73	0.007
Dissection	4.57	1.08–19.59	0.041
Increase in creatinine level	3.57	1.1–11.62	0.035
Increase in lesion length	0.97	0.94–1.0	0.036

PCI = percutaneous coronary intervention; Ref = reference value; TIMI = Thrombolysis In Myocardial Infarction

*Hosmer-Lemeshow goodness-of-fit statistic, P=0.316; area under the receiver operating characteristic curve=0.761 (95% confidence interval, 0.688–0.834; P <0.001).

$P \leq 0.05$ was considered statistically significant.

TABLE IV. In-Hospital and One-Year Clinical Outcomes

Outcome	Total (N=269)	Procedural Success (n=221)	Procedural Failure (n=48)	*P* Value
In-Hospital				
Dissection	11 (4.1)	6 (2.7)	5 (10.4)	0.029
Coronary artery perforation	3 (1.1)	0	3 (6.3)	<0.001
Myocardial infarction	16 (5.9)	15 (6.8)	1 (2.1)	0.319
Q-wave	3 (1.1)	3 (1.4)	0	0.999
Non-Q-wave	13 (4.8)	12 (5.4)	1 (2.1)	0.475
One-Year				
Major adverse cardiac event	13 (4.8)	4 (1.8)	9 (18.8)	<0.001
Cardiac death	2 (0.7)	1 (0.5)	1 (2.1)	0.326
Target-vessel revascularization	10 (3.7)	2 (0.9)	8 (16.7)	<0.001
Target-lesion revascularization	1 (0.4)	1 (0.5)	0	0.999
Coronary artery bypass grafting	9 (3.3)	1 (0.5)	8 (16.7)	<0.001

Data are presented as number and percentage. $P \leq 0.05$ was considered statistically significant.

occurred during hospitalization. Except for dissection and perforation, which were significantly more frequent in the procedural-failure group, there was no significant difference between the 2 groups with respect to procedural and in-hospital complications.

One-Year Occurrence of Major Adverse Cardiac Events

Complete follow-up was achieved in 95.05% of the patients (mean duration, 15.06 ± 3.15 mo). Table IV shows that one-year MACE occurred in 13 patients (4.8%), with a predominance of TVR (3.7%). The overall prevalence of MACE was significantly lower in the patients who underwent successful PCI (1.8% vs 18.8% in the failure group; P <0.001). One patient in the success group underwent TVR (PCI in the same vessel) and target-lesion revascularization (repeat PCI because of in-stent restenosis) during the follow-up period. Procedural failure was significantly associated with more frequent need for TVR and CABG during the follow-up period (Table IV). Figure 1 shows the Kaplan-Meier cumulative MACE-free and CABG-free survival estimates. Included in the multivariate model were all the variables that had a significant relationship with one-year MACE in the univariate analysis (P <0.15, results not shown)—side branches, presence of bridging collateral vessels, number of diseased vessels, vascular site of chronic occlusion, absence of tapered-

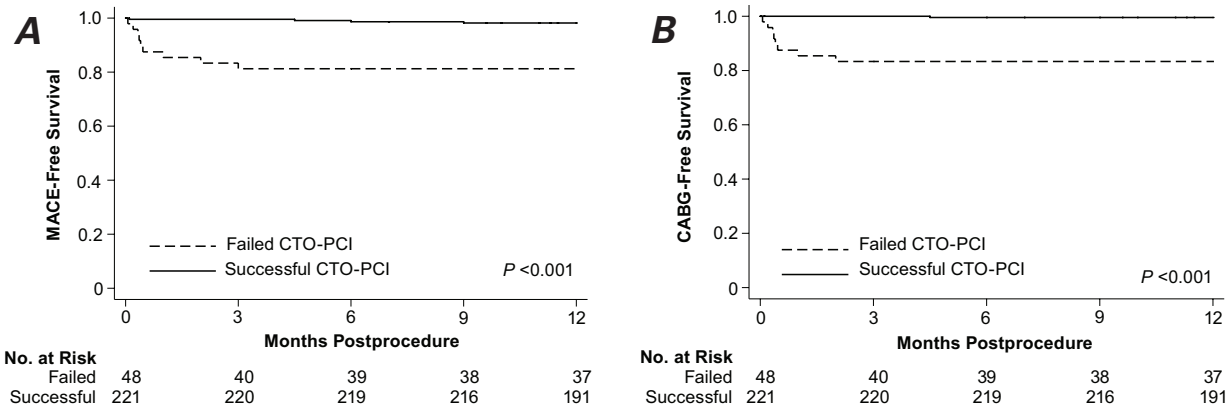

Fig. 1 *Kaplan-Meier cumulative **A**) MACE-free and **B**) CABG-free survival estimates in patients who underwent successful and failed percutaneous coronary intervention for chronic occlusion.*

CABG = coronary artery bypass grafting; CTO = chronic total occlusion; MACE = major adverse coronary event; PCI = percutaneous coronary intervention

stump structure, moderate-to-severe calcification, TIMI flow grade of 1 before PCI, hypertension, age, creatinine level, lesion length, and technical success. Only technical success was powerfully associated with a lower incidence of one-year MACE (HR=0.09; 95% CI, 0.03–0.30; P <0.001).

Discussion

The results of our study support PCI as an effective and safe therapeutic option in properly selected CTO patients because of the high success rate (82.2%) and the low prevalence of complications. Upon multivariate analysis, the most powerful predictors of technical failure were PCI for ostial lesions, the number of diseased vessels, and the occurrence of dissection during the procedure. Other independent predictors of technical failure were the absence of tapered-stump structure, a TIMI flow grade of 0 before PCI, and an increase in serum creatinine level or lesion length. One-year MACE occurred in 13 patients (4.8%), with a predominance of TVR (3.7%). Upon multivariate analysis, the only independent predictor of MACE was the technical failure of PCI.

Our technical success rate was within the range reported in several single-center studies (51%–85%).[1,9-12,19] No in-hospital deaths occurred among the patients in our study, and no emergent CABG was necessary during their hospitalization. These results, which agree with those previously reported,[1,8,11] imply that PCI for chronic occlusion is a safe procedure for the patients.

Because evaluating potential success is important before attempting PCI in chronically occluded lesions, investigators have designed various studies to identify influential factors.[1,2,8,12,19,20] Despite the reported findings, debate continues in regard to the impact of different clinical and angiographic variables on technical success and long-term clinical outcome.[3] Several angiographic factors, including the absence of tapered-stump structure,[21-26] the presence of bridging collateral vessels,[23] and the presence of a side branch at the occlusion site,[23,24] have been reported as predictors of technical failure. Severe tortuosity and moderate-to-severe calcification have also been reported as predictors of technical failure.[8,21,25-27] Still other investigators have concluded that multivessel disease and lesion lengths >15 mm predict technical failure.[1,8,11,19,21] Our results confirm some of the aforementioned conclusions but not others. For instance, calcification, bridging collateral vessels, and side branches at the occlusion site—identified as negative predictors of success in previous studies—had no predictive value in our study. This incongruity might be explained by variation in definitions and durations of chronic occlusion in previous studies. In addition, some large studies did not include information about important variables such as angiographic structure.[8,12,28]

Our study is one of the few to evaluate predictors of one-year MACE in patients who have undergone PCI as treatment for CTO. In line with previous investigations, our results confirmed the importance of technical success as a predictor of MACE-free survival. Initially successful PCI was the only predictor of one-year MACE-free survival in a large, multicenter, observational study.[1] In a retrospective study,[2] multivessel disease was the most powerful predictor of 5-year MACE; other independent predictors were successful recanalization and lack of stent implantation.

Previous investigators have emphasized the predictive impact of lesion lengths >15 mm on technical success.[1,11,19] Although lesion length had predictive value for technical failure in our study, its impact was less than in the aforementioned studies. This finding might be a consequence of improved devices, techniques, and op-

erator experience, which decreases the negative impact of lesion length on technical success. Further studies are necessary for confirmation.

Limitations of the Study

The number of cases in our failure group was relatively small and was 3 times lower than the number in the success group, which can affect the power of our study and our findings. Because the reported success rates of PCI in CTO vary from 51% to 85%, such a problem has been observed in previous observational studies. However, in our study, the frequencies of most variables that were not significantly different between the 2 groups of patients were very close together (Tables I and II), and the results would not seem to change if the sample size were larger. A second limitation is that no predictor for death, MI, or CABG could be identified in this analysis. The present study's retrospective nature with observational analysis of outcome is another limitation. For instance, some advanced technical approaches and new devices were not available in our center at the time of the study. Finally, detailed data about postprocedural medication were not available in our registry.

Conclusion

In properly selected patients who have coronary CTO, we conclude that PCI can be an effective and safe therapeutic option, with a high success rate and low prevalence of complications. Nonetheless, inconsistencies persist in regard to predictors of procedural success and long-term outcome. This suggests that large, prospective, multicenter studies with accurate inclusionary criteria and long-term follow-up periods are necessary to clarify these predictive factors. When the predictors are identified conclusively, they might aid the selection of patients and lesions for PCI, and contribute to the development of new methods and technologies designed to improve the procedural success rate of PCI in patients who have CTO.

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