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Predictors of Reocclusion After Successful Drug-Eluting Stent–Supported Percutaneous Coronary Intervention of Chronic Total Occlusion

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Objectives This study sought to assess the incidence of reocclusion and identification of predictors of angiographic failure after successful chronic total occlusion (CTO) drug-eluting stent–supported percutaneous coronary intervention (PCI).

Background Large registries have shown a survival benefit in patients with successful CTO PCI. Intuitively, sustained vessel patency may be considered as a main variable related to long-term survival. Very few data exist about the angiographic outcome after successful CTO PCI.

Methods The Florence CTO PCI registry started in 2003 and included consecutive patients treated with drug-eluting stents for at least 1 CTO (>3 months). The protocol treatment included routine 6- to 9-month angiographic follow-up. Clinical, angiographic, and procedural variables were included in the model of multivariable binary logistic regression analysis for the identification of the predictors of reocclusion.

Results From 2003 to 2010, 1,035 patients underwent PCI for at least 1 CTO. Of these, 802 (77%) had a successful PCI. The angiographic follow-up rate was 82%. Reocclusion rate was 7.5%, whereas binary restenosis (>50%) or reocclusion rate was 20%. Everolimus-eluting stents were associated with a significantly lower reocclusion rate than were other drug-eluting stents (3.0% vs. 10.1%; $p = 0.001$). A successful subintimal tracking and re-entry technique was associated with a 57% of reocclusion rate. By multivariable analysis, the subintimal tracking and re-entry technique (odds ratio [OR]: 29.5; $p < 0.001$) and everolimus-eluting stents (OR: 0.22; $p = 0.001$) were independently related to the risk of reocclusion.

Conclusions Successful CTO-PCI supported by everolimus-eluting stents is associated with a very high patency rate. Successful subintimal tracking and re-entry technique is associated with a very low patency rate regardless of the type of stent used. (J Am Coll Cardiol 2013;61:545–50) © 2013 by the American College of Cardiology Foundation

Large registries have shown a survival benefit in patients with successful chronic total occlusion (CTO) percutaneous coronary intervention (PCI) as compared to unsuccessful or unattempted CTO PCI (1–4). Intuitively, sustained vessel patency may be considered as a main variable related to long-term survival. Very few data exist about the angiographic outcome of successful CTO PCI, because randomized studies comparing different types of stents had small sample sizes; most registries did not include angiographic follow-up; and sparse data are available from a few small registries with a very low angiographic follow-up rate (4–12). The aim of this study was to assess the incidence of reocclusion and identification of predictors of angiographic failure after successful drug-eluting stent (DES)–supported CTO PCI.

See page 551

Methods

Patients and treatment. The Florence CTO PCI registry, started in 2003, includes consecutive patients treated with DES for at least 1 CTO. Details on this registry have been previously published (4,10). CTO was defined as a coronary obstruction with TIMI (Thrombolysis in Myocardial Infarction) flow grade 0 with an estimated duration >3 months. The duration of the occlusion was determined by the interval from the last episode of acute coronary syn-

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JACC Vol. 61, No. 5, 2013
February 5, 2013:545–50

Abbreviations and Acronyms

CI = confidence interval(s)
CTO = chronic total occlusion
DES = drug-eluting stent(s)
EES = everolimus-eluting stent(s)
HR = hazard ratio(s)
OR = odds ratio(s)
PCI = percutaneous coronary intervention
STAR = subintimal tracking and re-entry
TIMI = Thrombolysis In Myocardial Infarction

drome, or in patients without a history of acute coronary syndromes, from the first episode of effort angina consistent with the location of the occlusion or by a previous coronary angiography. In patients without a history of angina and who were admitted for an acute coronary syndrome or ST-segment elevation acute myocardial infarction with a definite identification of the culprit vessel, associated total occlusion of a nonculprit vessel was considered as a chronic occlusion if there was angiographic evidence of filling the vessel through collaterals. The indication for the percutaneous treatment of CTO was the demonstration of viable myocardium in the territory of the occluded vessel by echographic or scintigraphic provocative tests, whereas no CTO angiographic characteristic was considered as an absolute contraindication to PCI attempt. Thus, patients with long occlusions, extensive calcification, bridging collaterals, a nontapered stump, or a side branch at the occlusion site were included. Occlusion length was assessed from the beginning of the occlusion to the distal antegrade or retrograde vessel by filling from bridge collaterals or collaterals provided by a coronary artery other than the CTO vessel and using simultaneous contrast medium injection in both right and left coronary arteries. All occlusions were attempted using the anterograde or retrograde approach and dedicated coronary wires (hydrophilic and nonhydrophilic) and devices. The anterograde approach was the first option treatment in all but right coronary ostium CTO. Subintimal tracking and re-entry (STAR) technique was used only after failed anterograde and retrograde approaches. Three types of DES were used during the study period: first-generation sirolimus-eluting stent (Cypher, Cordis Corp., Miami Lakes, Florida), first-generation paclitaxel-eluting stent (Taxus Express or Taxus Liberté, Boston Scientific, Natick, Massachusetts), and everolimus-eluting stent (EES) (either Xience V, Abbott Vascular, Santa Clara, California; or Promus, Boston Scientific). Standard stent implantation techniques, including minimum overlap between stents and routine post-dilation using final high balloon pressure (≥16 atm) were used. All patients were pre-treated with aspirin (300 mg/day) and clopidogrel (loading dose 600 mg). Aspirin (300 mg/day) was continued indefinitely and clopidogrel (75 mg/day) for at least 12 months.

Procedural success was defined as a final diameter stenosis <30% with a TIMI flow grade 3 of the CTO vessel without death, or Q-wave myocardial infarction, or emergency coronary surgery. A Q-wave myocardial infarction was defined as new Q waves in 2 or more contiguous leads in addition to creatine kinase-myocardial band elevation. Creatine kinase-myocardial band fraction was routinely assessed 12 h after PCI in all patients or at least 3 times every 6 h in patients with recurrent chest pain.

All patients had scheduled clinical and electrocardiographic examinations at 6 months and at 1 and 2 years. All other possible information derived from hospital readmission or by the referring physician, relatives, or municipality live registries were entered into the prospective database.

All patients with successful CTO PCI and without moderate or severe renal insufficiency were scheduled for angiographic follow-up at 6 to 9 months. Unscheduled angiography was allowed based on clinical indication. Angiographic parameters were assessed using a computer analysis system (Innova 2100IQ, General Electric Healthcare Technologies, Little Chalfont, Buckinghamshire, United Kingdom).

Endpoints. The primary endpoint of the study was reocclusion of the CTO vessel at the scheduled or unscheduled angiographic follow-up. The secondary endpoints were: 1) binary angiographic restenosis; 2) 1-year major adverse cardiac events including death, myocardial infarction, and target CTO vessel revascularization; and 3) definite CTO stent thrombosis. Reocclusion was defined as a TIMI flow grade 0 to 1 in the target vessel, whereas restenosis was defined as >50% luminal narrowing at the segment site including the stent and 5 mm proximal and distal to the stent edges. For patients with multiple treated CTO, only the first CTO attempted was considered for the analysis. All deaths were considered cardiac unless otherwise documented. Stent thrombosis was defined according to the Academic Research Consortium criteria (13).

Statistical analysis. Discrete data are summarized as frequencies and continuous data as mean ± SD or median and interquartile range. Chi-square test or Fisher exact test analyses were used for comparison of categorical variables. The multivariable analysis to evaluate the independent contribution of clinical, angiographic, and procedural variables to reocclusion and in-segment restenosis was performed by forward stepwise logistic regression analysis. The following variables were tested: diabetes mellitus; renal insufficiency; CTO stent length >40 mm; STAR technique; EES; year of the index procedure. Cumulative survival analyses were performed using the Kaplan-Meier method, and the difference between curves was assessed by log-rank test. A multivariable analysis by forward stepwise Cox proportional hazards model was performed to evaluate the independent predictors of death, myocardial infarction, and target CTO vessel revascularization. The following variables were tested: age >75 years; diabetes mellitus; previous myocardial infarction; renal insufficiency; acute coronary syndrome at admission; left ventricular ejection fraction <0.40; 3-vessel disease; CTO vessel; CTO stent length >40 mm; STAR technique; EES; completeness of revascularization; year of the index procedure. Interaction between EES and year of the index procedure was tested

with multivariable regression models. Odds ratios (ORs), hazards ratios (HRs), and their 95% confidence intervals (CIs) were calculated.

A propensity score-matched analysis (1:1) was also performed to reduce bias due to a different time frame in the use of first-generation (paclitaxel- and sirolimus-eluting) and second-generation (everolimus-eluting) DES. An optimal data-matching technique was performed using propensity score as caliper. Propensity score analysis was performed with the use of a logistic regression model from which the probability for the use of EES was calculated for each patient. The variables entered into the model were: age >75 years; male; diabetes mellitus; left ventricular ejection fraction <0.40; 3-vessel disease; CTO vessel; CTO length >20 mm; CTO vessel reference diameter <2.5 mm; CTO heavy calcification; CTO stent length >40 mm; adjunctive rotational atherectomy; STAR technique; completeness of revascularization. Model discrimination was assessed with the C-statistic and goodness of fit with the Hosmer-Lemeshow test.

All tests were 2-tailed. A p value <0.05 was considered significant. Analyses were performed using the software package SPSS (version 11.5, SPSS Inc., Chicago, Illinois).

Results

From 2003 to 2011, 1,035 patients underwent a PCI attempt for at least 1 CTO. Of these, 802 (77%) had a successful PCI.

Table 1 summarizes the baseline patient characteristics. The mean age was 68 ± 11 years; 25% of patients had diabetes mellitus; and one-half of patients had a history of myocardial infarction. The majority of patients had multivessel disease, and 3-vessel disease was revealed in 49%. One-hundred and twenty-two patients were treated for 2 or 3 CTO.

Table 2 summarizes the procedural characteristics. Overall, multivessel PCI was performed in 67% of cases, and a complete revascularization was achieved in 84% of patients.

The STAR technique was used in 54 patients: recanalization was achieved in 50 cases, whereas a final TIMI flow grade of 3 was achieved in only 34 (4.2%); and EES was used in 16 (47%).

First-generation DES were used in 66% of cases, whereas EES were used in 34%.

Table 3 summarizes the angiographic and clinical outcomes. Of 802 patients, 49 were not eligible for angiographic follow-up because of death (n = 29: 26 cardiac deaths and 3 noncardiac deaths) or moderate (n = 10) or severe (n = 10) renal insufficiency. Thus, 753 patients were eligible for the angiographic follow-up , and 616 had coronary angiography (follow-up rate: 82%). All eligible patients who did not undergo angiographic follow-up were alive and asymptomatic for angina.

The target CTO vessel reocclusion was revealed in 46 patients (reocclusion rate: 7.5%). The reocclusion rate was 10.1% in patients treated with first-generation DES, and 3% in patients treated with EES (p = 0.001). The reocclusion rate was 57% in patients treated using the STAR technique and 5.1% using non-STAR techniques (p < 0.001). Of 25 patients treated successfully using the retrograde approach, angiographic follow-up was available for 19, and no reocclusion was revealed. Nonocclusive restenosis was revealed in 79 patients (nonocclusive restenosis rate 13%).

There was no significant interaction between EES and year of the index procedure.

By multivariable analysis, the only variables related to reocclusion were the STAR technique (OR: 29.5, 95% CI: 11.9 to 73.2; p < 0.001) and EES (OR: 0.22, 95% CI: 0.09 to 0.54; p = 0.001). The only variable related to the risk of nonocclusive restenosis was the right coronary artery CTO (OR: 1.64, 95% CI: 1.02 to 2.62, p = 0.040).

At 1-year follow-up, the cardiac mortality rate was 3.2%, the myocardial infarction rate was 0.9%, whereas 103 patients (12.8%) underwent repeat PCI for restenosis or reocclusion of the CTO target vessel. Major adverse cardiac events rate was significantly lower in EES than in first-generation DES (11.6% vs 19%; p = 0.005). The target CTO revascularization rate was 14.1% in patients treated with first-generation DES, and 10.5% in patients treated with EES (p = 0.139). No patient underwent coronary surgery. Overall, the 3-year event-free survival rate (median:

Table 1 Baseline Clinical and Angiographic Characteristics

	Successful CTO PCI (n = 802)
Age, yrs	68 ± 11
>75	233 (29)
Male	680 (85)
Hypertension	485 (60)
Hypercholesterolemia	458 (57)
Current smokers	158 (20)
Diabetes mellitus	200 (25)
Previous myocardial infarction	405 (50)
Previous PCI	289 (36)
Previous coronary surgery	91 (11)
Renal insufficiency, creatinine >250 μmol/l	18 (2.2)
ACS	255 (32)
LVEF	44 ± 12
<40%	298 (37)
Multivessel disease	660 (82)
3-vessel disease	393 (49)
CTO vessel	
LAD	248 (31)
LCX	177 (22)
RCA	329 (41)
Others	48 (6)

Values are mean ± SD or n (%).

ACS = acute coronary syndrome(s) (includes unstable angina and non–ST-segment elevation myocardial infarction); CTO = chronic total occlusion; LAD = left anterior descending artery; LCX = left circumflex; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; RCA = right coronary artery.

JACC Vol. 61, No. 5, 2013
February 5, 2013:545–50

Table 2 Procedural Characteristics

	Successful CTO PCI (n = 802)
Occlusion length, mm	
Mean	38 ± 21
Median	32 (22–50)
Length >20	597 (74)
Reference CTO vessel diameter, mm	
Mean	2.63 ± 0.53
Median	2.60 (2.30–3.0)
Diameter ≤2.5 mm	190 (24)
Adjunctive rotational atherectomy	37 (4.6)
STAR technique	34 (4.2)
CTO stent implanted, n	1,509
Mean stents/patient	1.88
First-generation DES (PES and SES), %	66
EES, %	34
CTO stent length, mm	
Mean	52 ± 30
Median	44 (28–69)
CTO stent length >40	432 (54)
Post-PCI minimum lesion diameter, mm	
Mean	2.74 ± 0.49
Median	2.80 (2.50–3.0)
Fluoroscopic time, min	
Median	24 (15–36)
Contrast, ml	
Median	300 (200–400)
Multivessel PCI	540 (67)
Completeness of revascularization	675 (84)

Values are mean ± SD, median interquartile range, or n (%).
DES = drug-eluting stent(s); EES = everolimus-eluting stent; IQR = interquartile range; PES = paclitaxel-eluting stent(s); SES = sirolimus-eluting stent(s); STAR = subintimal tracking and re-entry; other abbreviations as in Table 1.

21 months) was 76 ± 2%. The 3-year event-free survival rate was 55 ± 14% in patients treated with the STAR technique, and 77 ± 2% in patients treated with a non-STAR technique (p = 0.014) (Fig. 1). At multivariable analysis by Cox analysis, the variables related to cardiac mortality were: age >75 years (HR: 4.64, 95% CI: 2.19 to 9.83; p < 0.001); left ventricular ejection fraction <0.40 (HR: 7.25, 95% CI: 2.77 to 19; p < 0.001); left anterior descending artery CTO (HR: 2.39, 95% CI: 1.13 to 4.33; p = 0.020); complete revascularization (HR: 0.48, 95% CI: 0.24 to 0.95; p = 0.037). Variables related to major adverse cardiac events were: age >75 years (HR: 1.64, 95% CI: 1.17 to 2.31; p = 0.004); STAR technique (HR: 2.26, 95% CI: 1.21 to 4.22; p = 0.010); left ventricular ejection fraction <0.40 (HR: 1.47, 95% CI: 1.06 to 2.06; p = 0.023); left anterior descending artery CTO (HR: 1.42, 95% CI: 1.02 to 2.01; p = 0.046) (Table 4).

Definite stent thrombosis rate was 0.4%.

Table 5 summarizes the matched comparison between patients treated with first-generation DES and EES (C-statistic: 0.69 and Hosmer-Lemeshow test p = 0.803 for propensity score analysis). Patients treated with EES had better clinical and angiographic outcomes.

Table 3 Clinical and Angiographic Outcomes

	Successful CTO PCI (n = 802)
1-year clinical outcome	
MACE	131 (16)
Cardiac death	26 (3.2)
Myocardial infarction	7 (0.9)
CABG	0
CTO vessel repeat PCI	103 (12.8)
First-generation PES and SES	72/508 (14.1)
EES	31/294 (10.5)
STAR	11/34 (32.3)
Definite stent thrombosis	4 (0.4)
Angiographic outcome (n = 616)	
Follow-up rate	616/753 (82)
In-segment restenosis or reocclusion	125 (20)
Reocclusion rate	46 (7.5)
First-generation PES and SES	39/385 (10.1)*
EES	7/231 (3.0)
STAR	16/28 (57)

Values are n (%). *p = 0.001 first-generation DES versus second-generation EES.
CABG = coronary artery bypass graft; EES = everolimus-eluting stent(s); MACE = major adverse cardiac event(s); other abbreviations as in Tables 1 and 2.

Discussion

The main findings of this study can be summarized as follows: 1) The use of EES, as compared to first-generation

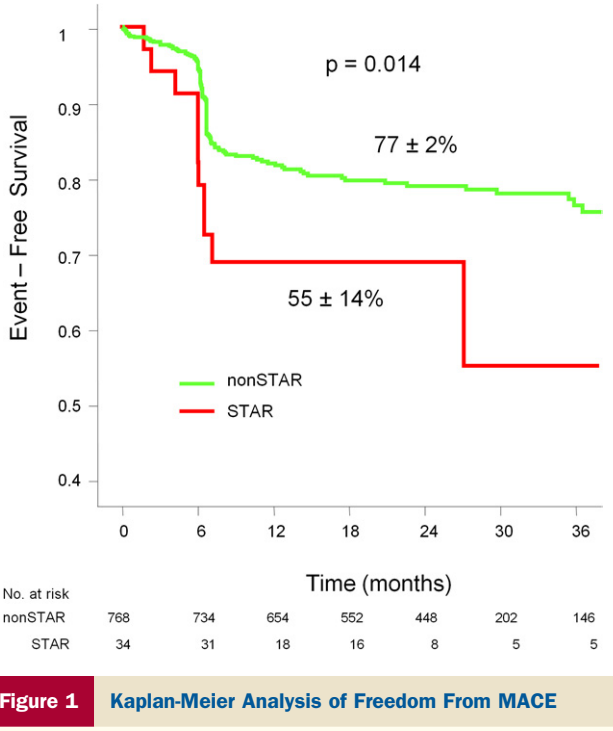

Figure 1 Kaplan-Meier Analysis of Freedom From MACE

Kaplan-Meier estimates of 3-year event-free survival in patients treated with the subintimal tracking and re-entry (STAR) technique **(red line)** and patients treated with a non-STAR technique **(green line).** MACE = major adverse cardiovascular events.

Table 4 Predictors of Clinical and Angiographic Outcome

Clinical Outcome	HR	95% CI	p Value
Cardiac death			
Age >75 yrs	4.64	2.19–9.83	<0.001
LVEF <40%	7.25	2.77–19	<0.001
LAD-CTO	2.39	1.13–4.33	0.020
Completeness of revascularization	0.48	0.24–0.95	0.037
MACE			
Age >75 yrs	1.64	1.17–2.31	0.004
STAR technique	2.26	1.21–4.22	0.010
LVEF <40%	1.47	1.06–2.06	0.023
LAD-CTO	1.42	1.02–2.01	0.046
Angiographic Outcome	**OR**		
Reocclusion			
STAR technique	29.50	11.9–73.2	<0.001
EES	0.22	0.09–0.54	0.001
Nonocclusive restenosis			
RCA-CTO	1.64	1.02–2.62	0.040

CI = confidence interval(s); HR = hazard ratio(s); OR = odds ratio(s); other abbreviations as in Tables 1 to 3.

sirolimus- and paclitaxel-eluting stents, was associated with a 5-fold decrease in CTO vessel reocclusion rate. 2) The reocclusion rate with EES was only 3%, and this finding drives the difference in event-free survival between patients treated with first-generation DES and EES. 3) The STAR technique allowed CTO vessel recanalization in nearly all cases but a final TIMI flow grade of 3 was achieved in approximately 60% of patients. 4) Patients with a successful STAR procedure (final TIMI flow grade of 3) had a very high rate of reocclusion.

The better performance of EES versus first-generation DES was shown in the SPIRIT (Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions) randomized studies (14–16) that excluded CTO patients, and also in the COMPARE (Second-Generation Everolimus-Eluting and Paclitaxel-Eluting Stents in Real-Life Practice) trial (17), an all-comer randomized study comparing EES with first-generation paclitaxel-eluting stents. However, this study did not provide data on the performance of EES in CTO that accounted for only 3.6% of treated lesions. The increased efficacy of EES in very long CTO lesions (requiring >40 mm stent length) as compared to first-generation paclitaxel-eluting stents was shown in a previous nonrandomized study (12). The current study confirms the increased efficacy of EES also in shorter CTO lesions.

There are very few data on angiographic follow-up after PCI using the STAR technique. In the original series of STAR technique applied to native coronaries described by Colombo et al. (18), 21 patients had angiographic follow-up, and the reocclusion rate was 24%. In a second series of 68 patients treated with the STAR technique, the reocclusion rate was 35% (19). However, in this study, the angiographic follow-up rate was only 56%. In a more recent series that included 74 patients, the reocclusion rate was 41% (follow-up rate: 85%) (20).

The current study shows a very high reocclusion rate (57%) after a successful CTO PCI using the STAR technique. This finding suggests limiting the use of this technique to a very few patients: patients with failed anterograde or retrograde attempt; patients with severe and refractory symptoms; and patients with a very high surgical risk despite a coronary anatomy suitable for bypass grafting.

Study limitations. This is a nonrandomized single-center study. Despite the shortcomings inherent in all registries, the study includes the largest series of CTO PCI patients with angiographic follow-up and provides original insights into the clinical and angiographic outcomes after successful DES-supported PCI for CTO. The number of patients treated with the STAR technique is small, preventing a definite conclusion on long-term efficacy of this technique. However, the reported high reocclusion rate is consistent with the rates reported in previously published small patient series (8,18,19).

Conclusions

The uses of EES and conventional anterograde or retrograde approaches to CTO are associated with very low rates of target vessel reocclusion. Conversely, the use of the STAR technique, even successfully, is associated with a very high rate of target vessel reocclusion.

Table 5 Baseline Characteristics and Outcome of the Propensity Matched Groups

	First-Generation DES (n = 294)	EES (n = 294)	p Value
Age >75 yrs	77 (26)	81 (28)	0.710
Male	259 (88)	261 (89)	0.796
Hypertension	168 (57)	185 (63)	0.152
Diabetes mellitus	64 (22)	73 (25)	0.380
Previous myocardial infarction	140 (48)	168 (57)	0.021
LVEF ≤40%	108 (37)	104 (35)	0.731
Three-vessel disease	136 (46)	130 (44)	0.619
LAD-CTO	107 (36)	96 (33)	0.340
Occlusion length >20 mm	251 (85)	244 (83)	0.429
Reference diameter ≤2.5 mm	63 (21)	63 (21)	1.00
CTO stent length >40 mm	187 (64)	193 (66)	0.605
Rotational atherectomy	9 (3.1)	12 (4.1)	0.505
STAR technique	12 (4.1)	16 (5.4)	0.439
Complete revascularization	249 (85)	260 (88)	0.183
1-year clinical outcome			
MACE	66 (22.4)	34 (11.6)	<0.001
Cardiac death	14 (4.8)	3 (1.0)	0.007
Myocardial infarction	8 (2.0)	1 (0.03)	0.019
CTO vessel repeat PCI	50 (17)	31 (10.5)	0.023
Definite stent thrombosis	3 (1.0)	0	0.082
Angiographic outcome	230	231	
In-segment restenosis or reocclusion	63 (27)	30 (13)	<0.001
Reocclusion	23 (10)	7 (3)	0.002

Values are n (%) or n.
Abbreviations as in Tables 1 to 3.

JACC Vol. 61, No. 5, 2013
February 5, 2013:545–50

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