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Original Article

Predictors of success in percutaneous Coronary intervention for chronic total occlusion

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ABSTRACT

We performed a retrospective analysis of 146 chronic total occlusion CTO patients to evaluate the antecedents of success and failure in CTO – Percutaneous Coronary Intervention (PCI) in Indian patients. The study aimed to identify the technical success rate, analyse immediate patient outcomes, and understand the factors impacting the successful outcomes. Our results showed that J-CTO (Multicenter CTO Registry of Japan) scores correlate well with the success rates of CTO-PCI and two most important factors deciding failure are lesion length more than 20 mm and lesions with calcification. Most important step to success of CTO is wiring, once wire crosses the segment, success rates of the procedure is around 97%. The wire escalation strategy has to be modified once the initial soft (polymer) wire fails, it's reasonable to use high tip load wire like conquest pro without the use of intermediate wires (except in presence of tortuosity). At 1 year follow up of these patients, there was a statistically significant drop in angina class and major adverse cardiac event rates in the successful CTO group.

1. Introduction

Interventional treatment of chronic total occlusions (CTO) in coronaries continues to be challenging. However, with the advancement in the percutaneous coronary Intervention (PCI) techniques, development of suitable hardware and operator skill, the procedural success has improved from 50 to 60% to 75–90% and therefore the procedure is now more frequently attempted.[1]

Various studies have highlighted the benefits of opening a CTO. The Mid-America Heart Study analysed 2007 patients over 20 years of performing PCI for CTOs. It showed that 10 years survival rates were higher in patients with successful CTO revascularization than in patients with failed attempts (74% vs 65% with p-value <0.001).[2] Another prospective study TOAST-GISE (Total Occlusion Angioplasty STudy—supported by Società Italiana di Cardiologia Invasiva) of 390 CTOs showed that a successful PCI was associated with a reduced 12 month incidence of cardiac death or myocardial infarction (MI) (1.1 vs 7.2%), a reduced need for coronary artery bypass surgery (CABG) (2.5 vs 15.7%) and greater freedom from angina (89 vs 75%).[3] The British Columbia Cardiac registry studied 1458 patients with CTOs, which constituted 15% of the attempted revascularizations. Successful PCI of CTOs was associated with increased survival and reduced need for revascularization over 7years follow-up.[4]

The goal of the present study was to evaluate the antecedents of success and failure in CTO –PCI in Indian patients. The study aimed to identify the technical success rate, analyse immediate patient outcomes, and understand the factors impacting the successful outcomes.

2. Material & methods

2.1. Study design and patient population

This is a retrospective analysis of 146 consecutive patients treated with PCI for CTO of native coronary arteries during the period of January 2010 to December 2014. It was performed at a single centre and the cases were performed by multiple operators. The indications for offering PCI intervention to CTO lesions were either clinical symptoms of ischemia, or demonstration of viable myocardium in the absence of symptoms and finally technical feasibility as judged by the operator himself.

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2.2. Definitions

A complete blockage of the native coronary vessel as seen on coronary angiography with no luminal continuity with TIMI (thrombolysis in myocardial infarction) flow grade 0 was defined as a total occlusion. The duration of the total occlusion needed to be more than 3 months. The duration was determined as an interval from the last clinical event such as MI, acute coronary symptoms, and angina wherever it was possible to assess from the history. Additional stenosis of >70% in more than one major artery was defined as multivessel disease. Severe tortuosity was defined as one or more vessel bending of $\geq 90^{\circ}$ or three or more vessel bending of 45–90°. The vessel was considered as calcified regardless of severity if any evident calcification is detected within the CTO segment. A funnel shaped occlusion at the proximal end with or without clear micro-channels was considered tapered stump whilst an abrupt occlusion without any micro-channels was considered blunt stump. Chronic Kidney disease (CKD) was defined as patients either on maintenance hemodialysis or with an e-GFR (glomerular filtration rate) of <60 ml/min (as calculated by MDRD (Modification of Diet in Renal Disease) study equation).

Technical success was defined as restoration of final TIMI III flow with a final diameter stenosis of <30%. A Q-wave MI was defined as new Q waves in 2 or more contiguous leads in addition to fivefold elevation in creatinine kinase-myocardial band elevation. All deaths were considered cardiac unless otherwise documented.

2.3. Interventional procedure

The patients were pretreated with aspirin and a P2Y12 receptor antagonist such as clopidogrel, prasugrel or ticagrelor before the procedure as per standard practice. Unfractionated heparin (UFH) remained the prime choice of anticoagulant during the procedure and was used in a manner to maintain activated clotting time between 300 and 350 s. Practically in all the patients activated clotting time was assessed every 30 min during the procedure to avoid thrombotic complications.

A J-CTO score was derived for each lesion based on the multicentre CTO registry of Japan and was validated to predict the guidewire crossing probabilities in less than 30 min.[5] J-CTO score calculations considered parameters such as previous failed attempts, calcification evident on angiography, bending within occluded segment, occlusion length of more than 20 mm and blunt proximal stump.[6] The SYNTAX scores were calculated for all the patients.[7] One independent experienced interventional cardiologist, who was blinded to the patient details and outcomes, verified the J-CTO score and SYNTAX score following a thorough observation of coronary angiograms.

2.4. Follow up

The patients were followed up at 1 year via either a clinic or a telephonic follow up: the composite clinical endpoint of major adverse cardiac events (MACE) includes cardiac death, MI, ST target lesion revascularization and CABG. The definitions of the above are as per standard definitions as outlined in Appendix A.

2.5. Statistical analysis

Continuous variables were presented as mean ± standard deviations (inter-quartile range and median if not normally distributed) and were compared using Student unpaired *t*-test. Categorical variables were presented as counts and percentages and compared with the chi-square test when appropriate (expected frequency >5). Otherwise, the Fisher exact test was used. A *p*-value of <0.05 was considered significant. All data were processed using the Statistical Package for Social Sciences, version 15 (SPSS, Chicago, IL, USA).

3. Results

A total of 146 lesions in 146 patients (137 men; mean age: 59.84 ± 10.86 years) were treated with PCI for CTO. Out of these, 105 patients (72%) (mean age: 58.65 ± 10.14 years) had successful PCI and was unsuccessful in 41 patients (28%) (mean age: 62.87 ± 12.12 years). The baseline demographic and clinical characteristics of the patients with successful and unsuccessful CTO PCI are given in Table 1. Although predisposing factors like diabetes (50.7%), hypertension (59.6%), and prior coronary artery disease (49.3%) was observed in significant no. of cases,there was no significant difference between the clinical and laboratory characteristics among the two groups, except mean age which was found to be higher in the unsuccessful CTO PCI group (58.65 ± 10.14 vs. 62.87 ± 12.12, p = 0.03).

Majority of the patients had multivessel disease (63%) and the right coronary artery (RCA) was the target vessel in most of the patients (43%). Complete lesion characteristics for both the groups are summarised in Table 2. Most patients (36.3%) presented with J-CTO score 2 and higher J-CTO score was associated with higher failure rates (p = 0.006). There were two very important factors deciding failure which include lesion length more than 20 mm (73.2%) (p = 0.007) and lesions with calcification (68.3%) (p = 0.0004). There was similar prevalence of severe tortuosity, blunt stump, collaterals, and ostial lesions amongst the two groups. However, none of them determined either success or failure.

Eleven patients (7.5%) who had one previous failed attempt of CTO PCI were treated with second attempt with success rate of 8 out of 11 (72%). Vast majority (n = 142) were treated using antegrade approach (97.2%) and the overall technical success rate was 72%. While there

Table 1
Baseline Patient Characteristics.

Baseline and demographic characteristics	Successful PCI n = 105	Unsuccessful PCI n = 41	p-value
Age, Mean ± SD	59.84 ± 10.86		
	58.65 ± 10.14	62.87 ± 12.12	0.0462
Gender, n (%)			0.2685
Male	100 (95.2)	37 (90.2)	
Female	5 (4.8)	4 (9.8)	
Medical History, n (%)			
Diabetes mellitus	50 (47.6)	24 (58.5)	0.234
Hypertension	61 (58.1)	26 (63.4)	0.555
Smokers	19 (18.1)	4 (9.8)	0.215
Prior Coronary artery disease	48 (45.7)	24 (58.5)	0.165
CKD/RENAL DYSFUNCTION	8 (7.6)	2 (4.9)	0.556

Table 2
Lesion Characteristics.

Parameter	Successful PCI n = 105	Unsuccessful PCI n = 41	p-value
Target Vessel, n (%)			0.53
LAD	40 (38.1)	14 (34.2)	
LCX − OM	24 (22.9)	7 (17.1)	
RCA	41 (39)	20 (48.8)	
Multivessel disease, n(%)			**0.41**
Single	41 (39)	13 (31.7)	
Multivessel	64 (61)	28 (68.3)	
Collaterals, n (%)			**0.60**
Ipsilateral	14 (13.3)	4 (9.8)	
Contralateral	81 (77.1)	31 (75.6)	
Bridging	10 (9.5)	6 (14.6)	
Syntax Score, n(%)			0.874
≤22	65 (61.9)	23 (56.1)	
23 to 32	25 (23.8)	10 (24.4)	
≥33	6 (5.7)	3 (7.3)	
NA	9 (8.6)	5 (12.2)	
J-CTO score, n (%)	Mean: 2.14 ± 1.62		<0.001
0	20 (19)	1 (2.4)	
1	37 (35.2)	11 (26.8)	
2	36 (34.3)	17 (41.5)	
3	12 (11.4)	12 (29.3)	
Length of CTO >20 mm, n (%)	51 (48.6)	30 (73.2)	<0.0001
Calcification, n (%)	38 (36.2)	28 (68.3)	<0.001
Severe tortuosity, n (%)	4 (3.8)	2 (4.9)	0.77
Blunt stump, n (%)	43 (41)	17 (41.5)	0.952
Side Branch angle >70, n (%)	2 (1.9)	2 (4.9)	0.32
Sidebranch >1.5 MM, n (%)	19 (18.1)	6 (14.6)	0.62
Osteal lesions, n (%)	10 (9.5)	8 (19.5)	0.099

was no significant difference between the procedural time between the groups; the amount of contrast used (p = 0.001) and number of wires used to cross the CTO (p = 0.0001) was significantly higher in the unsuccessful CTO PCI group. In 3 cases, the CTO was crossed but the micro-catheter or balloon catheters could not cross. These were classified as unsuccessful CTO attempts.

Complete details of the angiographic and procedural characteristics for the two groups are given in Table 3.

As shown in Table 4, in almost half of the patients 71 (48.6%), the lesion was successfully crossed with a maximum of two wires. As shown in Table 5, the common wires which successfully crossed the segment included Conquest pro family, Fielder family, Pilot 150 and Ultimate 3.

Procedural complications such as coronary dissection, coronary perforation, and cardiac tamponade occurred in 25 patients (17.1%). However, the complications rates were similar among both the groups (p > 0.05). One patient in the unsuccessful CTO PCI had cardiac tamponade due to peroration in the left anterior descending (LAD) artery and was treated with pericardiocentesis. There were total of 3 in-hospital deaths, 2 of which occurred in the successful group and 1 in the unsuccessful group. Details about complications and in-hospital outcomes are given in Table 6.

Table 3
Angiographic and Procedural Characteristics.

Parameter	Successful PCI n = 105	Unsuccessful PCI n = 41	p-value
Number of CTO attempted, n (%)			
First attempt	97 (92.4)	38 (92.7)	NS
Second attempt	8 (7.6)	3 (7.3)	NS
Antiplatelet Therapy, n (%)			NS
Clopidogrel	86 (81.9)	34 (82.9)	
Prasugrel	14 (13.3)	5 (12.2)	
Ticagrelor	5 (4.8)	2 (4.9)	
Number of wire used to cross, Mean ± SD	2.49 ± 1.19	3.85 ± 1.17	<.00001
Guide wire method, n(%)			0.067
Retrograde CTO	1 (1)	3 (7.3)	
Antegrade CTO	104 (99)	38 (92.7)	
Balloon used, Mean ± SD	2.06 ± 1.02	2.5 ± 1.9	0.265
Stent per lesion, Mean ± SD	1.57 ± 0.67	0 (0)	NA
Stent length, mm, Mean ± SD	28.01 ± 7.88	0 (0)	NA
Stent diameter, mm, Mean ± SD	2.66 ± 0.34	0(0)	NA
Penetration Technique			
Parallel wire technique, n (%)	9 (8.6)	12 (29.3)	0.001
Anchoring balloon technique, n(%)	5 (4.8)	3 (7.3)	0.54
Procedure time, min, Mean ± SD	56.77 ± 29.01	57.7 ± 33.7	0.933
Contrast volume, ml, Mean ± SD	337 ± 72	387 ± 97	0.0016
IVUS, n(%)	5 (4.8)	0 (0.0)	0.155
Rotablation, n(%)	2 (1.9)	0 (0.0)	0.373
IABP, n(%)	6 (5.7)	1 (2.4)	0.406
POBA, n(%)	7 (6.7)	2 (4.9)	0.69
Wire crossed in less than 30 min, n (%)	81 (77.1)	3 (7.3)	<0.001

Table 4
Number of wires that were used to cross the CTO successfully.

No of wires used	No. of patients
1	30
2	41
3	27
4	35
5	7
6	5
7	1

Table 5
Showing the wire that successfully crossed the CTO.

Wire that crossed	No. of Cases
Conquest Pro 12	20
Fielder FC	18
Fielder XT	13
Ultimate 3	12
Pilot 150	11
Fielder XTA	7
Miracle 4.5	6
Conquest pro 9	4
Pilot 200	3
Miracle 6	3
Miracle 3	2
Whisper MS	2
Fielder XTR	1
Gaia 1	1
Gaia 3	1
Grand Slam	1
Miracle 12	1
Stabilizer Plus	1
Whisper Es	1
BMW	1

Out of a total of 146 patients, 110 patients were followed up at 1 year via either a telephonic or a clinic follow up. Tables 7 and 8 show the one year clinical status and event rates after successful and unsuccessful CTO PCI patients. Fig. 2 shows the one year event free survival in the successful and unsuccessful CTO PCI patients. As evident in Table 7, a significantly lesser number of patients had angina in the successful PCI group. Similarly, the composite MACE rate which included cardiac death, ST, revascularization (PCI or CABG) and MI was higher in the unsuccessful PCI group and was statistically significant.

4. Discussion

Recent advances in hardware have made CTO PCI technique safe, effective, and efficient. Traditionally antegrade wiring approach was used first barring a few anatomical subsets. While the technique has been observed as the most time efficient technique in the case of successful CTO PCI, its success rates begin to dwindle with increasing complexity of the CTO lesion parameters such as lesion length, calcification, bridging collaterals, blunt stump, and poor distal vessel visualisation.[8]

Table 7
Angina class at one year follow up.

Angina class 1 year FU	Successful PCI	Unsuccessful PCI	p value
	n = 83	n = 27	0.047
0	75 (90.4)	19 (70.37)	
1	2 (2.4)	5 (18.52)	
2	6 (7.2)	3 (11.11)	
3	0 (0.00)	0 (0.00)	
4	0 (0.00)	0 (0.00)	

The overall success rate in our patients was 71.9%, which is comparable to other series. The Indian data by Gopakumar et al. showed a success rate of 68% in first attempt which increased to 71.42% in second attempt.[9] The most important factor for success of a CTO is successful wiring of the CTO segment. As shown in our study, once the wire crosses, the success rate is as high as 97.2% (105 out of 108). Morphology of the CTO lesion is considered to affect the guidewire crossing and therefore is the strongest predictor of failure of CTO PCI procedure.[10] While a plethora of the studies are available investigating the factors affecting the success of CTO PCI, debates continue to justify the impact of various clinical and angiographic factors on the technical success and clinical outcomes. The lesion parameters which are observed to reduce the success rate of CTO PCI include presence of blunt stump, presence of bridging collaterals, presence of side branch at occlusion site;[6,11] severe tortuosity, calcification;[12] multivessel disease, and lesion length >20 mm. [6,13] The results of the present study support only some of these observations. For instance, the presence of blunt stump, presence of bridging collaterals, and presence of side branch at occlusion site, severe tortuosity, and multivessel disease had no impact on the success or failure rate of CTO PCI in the present study. This variation in the observation might be due to variation in the devices and techniques used and improved operator's experience which dilutes the negative impact of lesion characteristics on technical success.

The J-CTO score is developed to predict the possibility of guidewire crossing the CTO within 30 min.[5] Higher the J-CTO score, higher probability of procedure failure. Our findings suggest that judicial use of wiring techniques and appropriate use of hardware are likely to overcome the impact of lesion complexity on the success rate. However, as shown in Fig. 1, the significant difference between the incidences of successful and unsuccessful CTO PCI ($p = 0.006$) with increasing J-CTO score further confirms the applicability of the scoring system in predicting PCI and should warn operators before attempting the case (Fig. 2).

As seen from Table 5 that Conquest Pro and Fielder family wires were most successful in crossing the CTO. The underlying explanation is that irrespective of presence or absence of a tapered stump and the duration of the CTO in comparatively softer lesion, the success is achieved by polymer jacketed wires by virtue of finding the microchannel in the CTO segment. On the other hand

Table 6
Complications and in-hospital clinical outcomes.

Clinical outcomes	Patients n = 146	Successful PCI n = 105	Unsuccessful PCI n = 41	p-value
Procedural complications				
Coronary dissection	15 (10.2)	10 (9.5)	5 (12.19)	0.63
Coronary perforation	9 (6)	5 (4.8)	4 (9.8)	0.26
Cardiac tamponade	1 (0.68)	0 (0)	1 (2.4)	0.107
Death	3	2	1	0.84
MI	0	0	0	–
Urgent revascularisation	0		0	–
Stroke	0	0	0	–

Table 8
MACE events at one year follow up.

Major adverse cardiac events at 1 year FU	Successful PCI	Unsuccessful PCI	p-value
	n = 83	n = 27	
Cardiac death	4 (4.82)	4 (14.81)	0.08
TLR	1 (1.20)	1 (3.70)	0.43
CABG	0 (0.0)	1 (3.70)	0.079
MACE	**5 (6.02)**	**6 (22.22)**	**0.015**

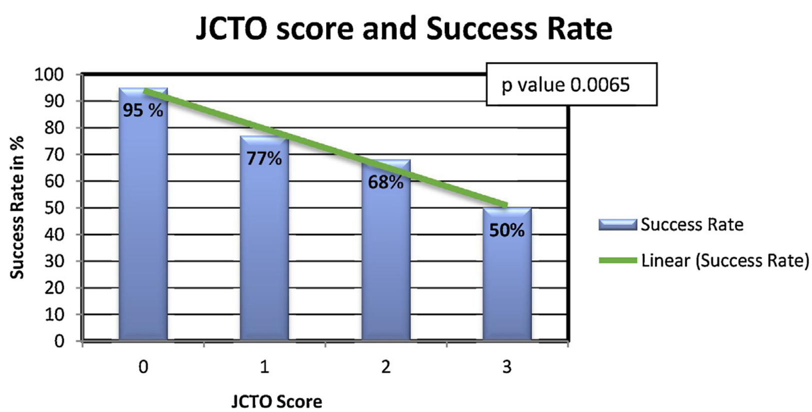

Fig. 1. Showing correlation between JCTO score and success rate. p value 0.0065.

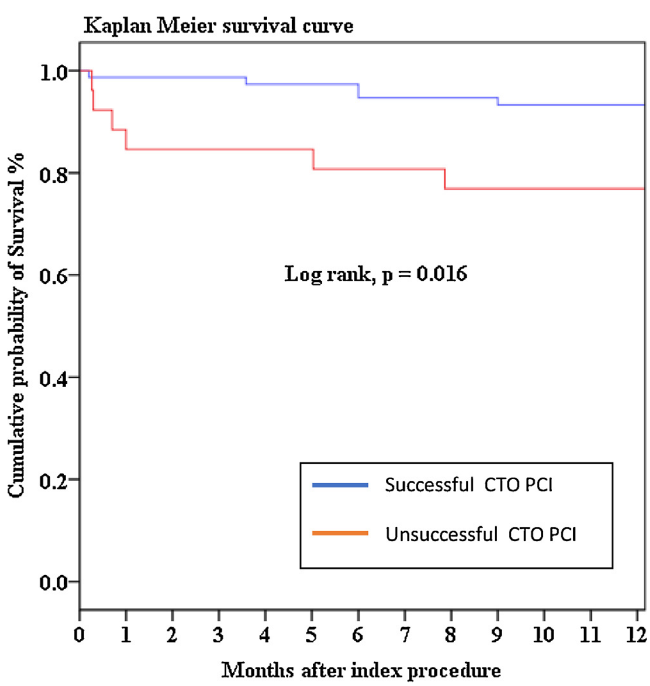

Fig. 2. Kaplan Meier survival curve for event free survival at one year in successful versus unsuccessful CTO PCI.

where the lesion is hard, Conquest series, especially conquest pro 12 was successful. This led us to believe that old fashioned wire escalation technique is not needed and if lubricious wire does not cross, one should consider proceeding to stronger wire without use of intermediate wire. Gaia series of wire were not available to us till very late, but after its availability, our strategy has changed. In a non-tapered stump, we often start with Gaia first or second and if unsuccessful, escalate to Conquest series.

One important limitation of conquest wires are that they are not very easily torquable and could fail to traverse through angulated or tortuous segment and even can cause dissection and perforation. In cases where we found that missing segment could be having angulations, our choice has been Ultimate bros over conquest pro wire. Immaculate knowledge of the wires properties; tip load, lubricity, torque responsiveness and tactile sensation makes the difference between success and failure with first or second wire selected.

Although technical success to treat CTO with PCI remains the goal of every interventional cardiologist, success should not be achieved at the cost of patient safety. Failure without complications is better than the success with severe complications. It is imperative that the operator understands the limitations and risks of each technique and instrumentation and uses them judiciously. Considering this ethical background, we refrained from aggressively attempting the lesions which were not easily passed. The incidence of coronary dissection (10.2%) and coronary perforation (6%) were similar to those reported in similar studies.[14,15] Although the complication rates were noted with higher percentage in unsuccessful group, these were similar to those in earlier published data. We also noticed that coronary perforation caused cardiac tamponade in only 1 (0.68%) patient which suggest that guidewire entry in the pericardial space without the introduction of balloon or microcatheter is unlikely to cause tamponade.

The clinical benefits of opening up a CTO remain controversial. Several observational studies have shown benefits of opening up of CTO such as improvement in symptoms, decreased event rates and improves survival.[1–4] These benefits were not confirmed by the recently published trials such as EXPLORE[16] and DECISION-CTO[17] which showed no significant advantages of opening up of a CTO. However, our study showed improvement in form of symptomatic relief and MACE outcomes at one year follow up in the successful PCI group. Our follow up was limited by high number of patients that were lost to follow up.

5. Conclusion

We reconfirm that the JCTO score has been useful as a predictability score in our study. The two important variables predicting failure are presence of long lesion and calcification. The wire escalation strategy has to be modified once the initial soft (polymer) wire fails, it's reasonable to use high tip load wire like conquest pro without the use of intermediate wires (except in presence of tortuosity).

Appendix A.

Endpoint	Definition
Cardiac Death	Cardiac death is defined as death by 1. Acute myocardial infarction 2. Cardiac perforation/cardiac tamponade 3. Arrhythmia and conduction disturbance 4. Cerebrovascular events suspected to be related to cerebral vascular events or procedures within 30 days of procedure 5. Death due to procedural complications 6. Cardiac causes cannot be ruled out death
MI	MI is defined as an abnormal cardiac biomarker level above the institutional upper limit of normal (either cardiac troponin or CK-MB), and either at least 1 of the following: a) Symptoms of myocardial ischemia, b) New or presumed new significant ST-segment–T wave (ST–T) changes or new LBBB on the ECG, c) Development of pathological Q waves on the ECG, d) Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality, e) Identification of an intracoronary thrombus by angiography or autopsy. In addition, periprocedural infarctions are defined as the following; Post procedure-related MI: Defined as the occurrence within 48 h after either PCI or CABG during follow-up. An elevated cardiac biomarker level (>5 times after PCI or >10 times after CABG), and either at least 1 of the following: a) New pathologic Q wave or new LBBB, b) Angiographically documented graft or native coronary artery occlusion or new severe stenosis with thrombosis and/or diminished epicardial flow, or, c) Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
Stent thrombosis	ARC (Academic Research Consortium Definitions) 1) Definite stent thrombosis: clinical manifestation of acute coronary syndrome with pathologic confirmation of thrombosis, obstruction, and acute thrombosis 2) Probable stent thrombosis: myocardial infarction of the target vessel without an unidentified death or thrombosis within the first 30 days 3) Possible stent thrombosis: Death unclear after 30 days Stent thrombosis can be 1) Acute: ≤1 day post-procedure 2) Subacute: >1 day and ≤30 days post-procedure 3) Late: >30 days and ≤1-year post-procedure 4) Very late: >1-year post procedure
Revascularization	A coronary revascularization procedure may be either a CABG or a PCI. The coronary segments revascularized will be sub-classified as: • Target Lesion: A lesion revascularized in the index procedure (or during a planned or provisional staged procedure). The length of the target lesion is inclusive of the treated section and the 5 mm proximal and distal to the treated section. • Target Vessel: The target vessel is defined as the entire major coronary vessel proximal and distal to the target lesion including upstream and downstream branches and the target lesion itself. • All revascularization events will be adjudicated as either ischemia-driven or non-ischemia-driven. Revascularization will be considered ischemia-driven if the diameter stenosis of the revascularized coronary segment is ≥50% by QCA and any of the following criteria for ischemia are met: a) History of angina pectoris, presumably related to the target vessel, b) Objective signs of ischemia at rest (electrocardiographic changes) or during exercise test (or equivalent), presumably related to the target vessel c) Abnormal results of any invasive functional diagnostic test (e.g., CFR or FFR). A target lesion revascularization for a diameter stenosis less than 50% might also be considered ischemia-driven by the Clinical Events Committee if there was a markedly positive functional study or ECG changes corresponding to the area served by the target lesion.

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