Percutaneous coronary intervention in the Occluded Artery Trial: Procedural success, hazard, and outcomes over 5 years

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Abstract

Background—The Occluded Artery Trial (OAT) was a 2,201-patient randomized clinical trial comparing routine stent-based percutaneous coronary intervention (PCI) versus optimal medical therapy alone in stable myocardial infarction (MI) survivors with persistent infarct-related artery occlusion identified day 3 to 28 post MI. Intent-to-treat analysis showed no difference between strategies with respect to the incidence of new class IV congestive heart failure, MI, or death. The influence of PCI failure, procedural hazard, and crossover on trial results has not been reported.

Methods—Study angiograms were analyzed and adjudicated centrally. Factors associated with PCI failure were examined. Time-to-event analysis using the OAT primary outcome was performed by PCI success status. Landmark analysis (up to and beyond 30 days) partitioned early hazard versus late outcome according to treatment received.

Results—Percutaneous coronary intervention was adjudicated successful in >87%. Percutaneous coronary intervention failure rates were similar in US and non-US sites, and did not significantly influence outcome at 60 months (hazard ratio for success vs fail 0.79, 99% CI 0.45–1.40, *P* = .29). Partitioning of early procedural hazard revealed no late benefit for PCI (hazard ratio for PCI success vs medical therapy alone 1.06, 99% CI 0.75–1.50, *P* = .66).

Conclusions—Percutaneous coronary intervention failure and complication rates in the OAT were low. Neither PCI failure nor early procedural hazard substantively influenced the primary trial results.

The Occluded Artery Trial (OAT), undertaken in 83 US and 134 non-US sites, showed no reduction in death, myocardial infarction (MI), or class IV heart failure when stable patients with persistent infarct artery occlusion underwent routine coronary recanalization using percutaneous coronary intervention (PCI) with stenting.[1]

Occluded Artery Trial eligibility defined an anatomically complex cohort with persistent coronary occlusion due to a combination of organizing thrombus, occlusive plaque disruption, or localized dissection. These features present technical challenges for PCI operators and have been associated with PCI failure and periprocedural complications.[2] The altered integrity of the downstream nonreperfused infarct zone may have been vulnerable to reperfusion injury.[3]

We report herein the adjudicated frequency and mechanisms of PCI failure and the nature and frequency of PCI-related complications in protocol-specified and early crossover procedures. Percutaneous coronary intervention results in US and non-US sites are compared, and the potential for PCI failure or an early PCI hazard to have influenced overall trial results is examined.

Methods

Funded by the National Heart, Lung, and Blood Institute, the OAT was an international, multicenter clinical trial testing the late open artery hypothesis through random assignment to early PCI-based coronary recanalization (PCI) or optimal medical therapy alone (MED). Supplementary funding and in-kind support from several corporate sources accounted for 6% of the study budget.[1] The authors were solely responsible for the design and conduct of this study, all analyses, the drafting and editing of the paper and its final contents.

The final cohort consisted of 2,201 patients (2,166 main trial between February 2000 and December 2005 + 35 OAT-NUC substudy extension between January and June 2006) enrolled at 217 sites in 25 countries. Study rationale, design, and primary results have been previously published.[1,4] Subjects were eligible if coronary angiography demonstrated persistent occlusion (thrombolysis in myocardial infarction [TIMI] grade 0 or 1 flow) of the infarct-related coronary artery calendar day 3 to 28 post MI. Patients were required to meet at least one high-risk criterion: proximal infarct-related artery (IRA) occlusion or ejection fraction <50%. Those with New York Heart Association class IV congestive heart failure, shock, spontaneous or provokable severe ischemia, 3-vessel, or left main coronary artery disease warranting bypass surgery (coronary artery bypass graft) were excluded. Participating PCI operators were required to document a case load of ≥75 PCIs per year, cumulative experience as principal operator of ≥500 interventions, and a major complication rate of ≤2% during the preceding year. Candidate sites submitted cineangiograms of recent PCI procedures targeting occluded target segments for review and certification.

Percutaneous coronary intervention procedure guidelines

Protocol-assigned PCI procedures were performed within 24 hours of study enrollment. When necessary, operators were expected to use various coronary guidewires with greater tip stiffness or lubricity. Although PCI technical success was defined centrally as <50% residual in-segment stenosis, operators were instructed to optimize the final result through complete coverage of the target occlusion and adjacent lesion shoulder (including dissection) with one or more locally approved bare metal or drug-eluting stents, seeking <20% residual diameter stenosis and normal flow. High-pressure stent deployment (≥14 bar) and glycoprotein 2b3a inhibitors (administered after guidewire crossing) and treatment of all significant lesions (>50% diameter stenosis) in other major segments of the target vessel were strongly encouraged.

Angiographic analysis

Diagnostic and protocol-assigned PCI cineangiograms were sent for central analysis and adjudication to the Cardiovascular Imaging Research Core Laboratory, University of British Columbia (directed by G.B.J.M. and C.E.B.). Quantitative analysis addressed the qualifying segment, proximal reference vessel diameter, antegrade and collateral flow grades, and target lesion dimensions (in-segment and in-stent) before and after PCI. The target lesion included the target occlusion and adjacent lesion shoulder >50% diameter stenosis. Target segments included additional 5 mm length proximal and distal perilesional zones. For consistency before and after recanalization, only proximal reference segments were used in calculations of percent diameter.[2,5] Qualitative analysis categorized assigned PCI procedures as successful, unsuccessful, or not attempted. Success was defined per protocol as <50% residual target segment stenosis with TIMI grade 2 or 3 flow. During central review, we also prospectively identified cases we deemed to be *technically successful* when final post-PCI flow remained less than TIMI-2 despite technical success in the target segment providing no epicardial cause for poor flow was present. Percutaneous coronary intervention failures were categorized by prespecified mechanisms including (i) failure to cross (most distal wire position proximal to a reconstituted distal segment), (ii) failure to reenter true lumen (most distal wire position at or beyond a reconstituted distal segment, but extraluminal), (iii) in-segment residual stenosis >50% for any reason, (iv) impaired distal runoff (TIMI flow 0 or 1) due to angiographically visible intraluminal thrombus or dissection, (v) other. More than one mechanism could apply. Baseline characteristics associated with PCI failure were examined.

Site-specific rates of angiographic procedural success were monitored. When procedure success fell <80% (after ≥5 protocol-assigned interventions) or when any procedural failure occurred during a site's first 4 assigned interventions, a review process addressing case-specific factors was initiated that engaged the site's investigators.

Complications and events

Complications were categorized as coronary perforation, proximal coronary dissection, or embolism causing or threatening ischemia in a nontarget territory, cardiac rupture, cardiac tamponade, major bleeding, vascular complication requiring surgical repair, ventricular arrhythmias requiring immediate intervention, stroke, or other. All recognized complications were counted, including multiple complications in a single patient. Complications were adjudicated as related or unrelated to PCI by an independent Morbidity and Mortality Classification Committee blinded to treatment assignment. Prespecified OAT end-point events were death, MI, or class IV congestive heart failure.[1,4]

PCI complications within 48 hours of study enrollment were examined using both intention-to-treat and treatment-received principles. Prespecified primary outcome events through 60 months of follow-up were analyzed by intention-to-treat, treatment-received, and PCI success status. Treatment-received analyses were based on treatment received within the first 30 days after randomization. The potential contribution of an early PCI hazard to overall trial results was explored by landmark analysis partitioning early (≤30 days) and late events (>30 days through 60 months) on an intention-to-treat basis.

Statistical methods

With the use of SAS version 9.1.3 (SAS Institute, Cary, NC), baseline characteristics were summarized as frequencies and percentages for categorical variables and as means with SDs or medians with interquartile ranges for continuous variables. Intergroup comparisons were performed using χ^2/Fisher exact test for categorical variables and Student t test or Wilcoxon rank test for continuous variables. Multivariable logistic regression model was developed to evaluate the relationship between baseline characteristics and successful PCI. Estimates of the

cumulative event rates were calculated by the Kaplan-Meier product-limit method, and groups were compared by the log-rank test of the 5-year curves.[6] Hazard ratio and 99% CIs were calculated by Cox proportional hazards regression models.[7] The OAT protocol prespecified a *P* value of .01 as the threshold for showing significant differences in all secondary analysis.

Results

Angiographic characteristics, PCI variables, and quantitative angiographic analyses are presented in Table I through Table III. Angiography was analyzed and adjudicated centrally in 2,183 (99.2%) of 2,201 patients enrolled. Percutaneous coronary intervention was attempted within 30 days of enrollment in 1,090 (99%) of 1,101 patients assigned PCI and in 33 (3%) of 1,100 patients assigned MED (Table II). Among PCI-assigned patients, stents were used in 86.1% and glycoprotein inhibitors in 66.7%. Procedures were deemed successful per protocol in 879 cases and technically successful in 65 additional cases. Combining these, we observed PCI success of 944 (87.3%) of 1,081 centrally adjudicated cases and in 953 (87.4%) of 1,090 attempts overall. Success rates and the use of stents and glycoprotein IIb/IIIa inhibitors were similar across coronary territories.

Mechanisms of PCI failure were adjudicated in 135 (99%) of 137 cases. Failure to fully cross the occluded segment with a guidewire was most common (n = 77, 57%), followed by failure to reenter true lumen (n = 34, 25%), residual stenosis >50% (n = 27, 20%), and extensive thrombus (n = 13, 10%). Percutaneous coronary intervention success rates were similar in US versus non-US sites (86.2% vs 86.7%, P = not significant). The incidence of prespecified procedural complications including early death or MI (<48 hours from enrollment) was low (Table IV). Core laboratory monitoring of adjudicated PCI success triggered protocol-specified review of PCI practices in 10 sites. Nine additional sites were reviewed after unexpected PCI failure observed in ≥1 individual cases. None required second review or termination.

Preprocedural characteristics of PCI-assigned patients are compared according to PCI success or failure in Table V. Of 50 characteristics examined, those independently predictive of failure were prior PCI (*P* < .001) and TIMI grade 0 (*P* = .007) with trends noted for Killip class ≥2 (*P* = .013) and male sex (*P* = .04).

Sixty-month estimates of death, MI, class IV HF, and their composite were similar when PCI-assigned subjects with successful PCI (per protocol or technical) were compared to those with PCI failure. This finding was not materially influenced by exclusion of those with technical success only. The as-treated analysis restricted to those PCI-assigned subjects with adjudicated PCI success versus MED-assigned subjects without crossover PCI within 30 days showed no difference in long-term outcomes either (Table VI, Figure 1). Finally, the landmark analysis examining the primary composite end point before and after 30 days showed statistically similar outcomes through 30 days (hazard ratio PCI/MED 1.4, 99% CI 0.8–2.4, *P* = .13). No difference in late outcome by intention-to-treat was seen among those surviving beyond 30 days (Figure 2).

Discussion

By resolving a longstanding controversy surrounding optimal care of MI survivors, publication of primary results from the OAT has influenced recent guidelines for management of MI.[8] The results of any single strategic trial testing the incremental value of medical or surgical procedures may be sensitive to the safety and efficacy with which the procedure in question has been delivered.[9] A thorough understanding of procedural outcomes and complications experienced in the procedural arm becomes especially relevant when weighing the external validity of these trials. Our report details the PCI procedural efficacy and remarkable safety across a wide range of countries within the OAT to provide this context.

The OAT incorporated design features intended to ensure objective measures of procedural outcomes. Principally, and despite the absence of angiographic end points per se, the trial used an expert core angiographic laboratory charged with reviewing all protocol-driven coronary angiographic images, including those recorded during protocol-assigned PCI procedures. Beyond conventional quantitative and qualitative measurements, this allowed independent adjudication of patient eligibility and, importantly, of PCI success. Furthermore, core review of PCIs allowed objective, standardized categorization of PCI failure modes as well as angiographically apparent complications such as perforation. Protocol adherence was excellent with >99% of all assigned PCI procedures, including 98.5% of failed PCI procedures so reviewed.

The OAT is by far the largest randomized interventional trial specifically examining PCI of nonacute coronary occlusions. It captured the practices of numerous selected operators from selected centers in 25 countries on 5 continents. We observed procedural success in 87.3% of attempted adjudicated procedures and in 81.4% of patients with core laboratory–determined TIMI flow 0 at baseline. Percutaneous coronary intervention success rates among 854 subjects assigned PCI at a non-US center were nearly identical to those 247 subjects assigned PCI at a major US center.

Our observed success rate is comparable to reports using routine stenting in similar populations. Yousef et al[10] reported PCI success in 30 (94%) of 32 patients assigned PCI for persistent left anterior descending IRA occlusion in The Open Artery Trial at 2 major British centers. The Open Artery Trial performed PCI 26 ± 17 days post MI, used a similar definition for PCI success, but required single-vessel coronary disease and did not use an independent core laboratory. The DECOPI trial performed at 16 centers in France and Belgium assigned 109 patients with persistent IRA occlusion to PCI performed a median of 8 days (interquartile range 5–11) after MI symptom onset.[11] Protocol-defined success required restoration of TIMI-3 flow and was reported in 82.2%, with TIMI-2 flow reported in an additional 4.7% (total 86.9%). In contrast, a survey of reports describing PCI in chronic coronary occlusions (age >12 weeks) found failure rates of 55% to 80%.[12]

The PCI failure modes we most commonly observed were incomplete coronary guidewire passage (failure to cross) and failure to reenter the true lumen distal to the occlusion (subintimal wire position). Although the incidence of failure is greater when treating chronic occlusions, Kinoshita et al[13] reported a similar distribution of failure modes in these patients (failure to cross 64%; subintimal wire position 24%). These shared modes of procedural failure reflect the limited precision in guidewire navigation inherent to current imaging. The association we and others have observed between TIMI-1 (as opposed to TIMI-0) baseline flow and PCI success is likely a consequence of the navigational clues provided by trace residual flow through microchannels. Improvements in guidewire navigation may therefore improve procedural results in subacute and chronic occlusions alike.

We observed several associations with PCI success/failure that were unexpected and may be due to chance. The apparent associations with low ejection fraction and prior PCI might be explained by covariance with unmeasured characteristics of advanced and complex coronary disease. The association with male sex is perplexing given the generally larger coronary arteries in men and is likely due to chance. Notable was the lack of observed association between PCI failure and presumed age of occlusion, whether expressed as median time from MI or as the proportion of patients undergoing PCI beyond 7 days from index MI. Presumably, healing that occurs during the first 4 weeks after initial occlusion precedes the development of dense fibrosis or calcification that accounts for higher PCI failure rates in truly chronic occlusions.

Failure of the OAT to demonstrate benefit attributable to a strategy of PCI ran counter to much previous experimental and observational data.[14] On one hand, negative OAT results may disprove the heretofore broadly accepted hypothesis that late infarct-artery patency is causally related to improved outcomes. Alternatively, the meaning of the OAT results may be biologically narrower, if no less clinically important. For instance, benefits attributable to late patency might have been offset by limitations of contemporary PCI. Percutaneous coronary intervention limitations apparent from the current analysis are several and include a significant primary failure rate plus a procedural hazard that included a small excess incidence of major complications and procedure-induced myonecrosis. To examine the potential influence of PCI failure, we compared long-term outcomes of those with successful versus unsuccessful protocol-assigned PCI (Figure 1, Table V). Although a weak trend favoring successful PCI was observed, there was no suggestion of benefit for the cohort with successful PCI compared to patients managed with medical therapy only. We note that a frequently cited report comparing long-term outcomes after PCI success versus failure in nonacute and chronic coronary occlusions did not include a medically treated control arm.[15] To examine the potential influence of early hazard, we performed a landmark analysis examining the primary end point before and after 30 days (Figure 2). There appears to be a nonsignificant excess of adverse events in the PCI arm up to 30 days. However, among those surviving beyond day 30, no suggestion of late benefit attributable to PCI, and by extension to late IRA patency, is seen. The absence of any signal for PCI benefit in these post hoc analyses suggests that persistent or recurrent IRA occlusion is merely a marker of another more fundamental characteristic that determines prognosis.

Limitations

Our analyses are primarily descriptive. Because of the small number of PCI failures (n = 137), there is limited statistical power to examine factors associated with failure or measure the effect of failure on outcome. The selection process for sites participating in the OAT was intended to enrich the study with expert center and operators. Percutaneous coronary intervention success rates achieved in less expert sites may be lower. Percutaneous coronary intervention complications may not be apparent on angiographic images; thus our estimate of rates is substantially dependent upon operator identification and voluntary site reporting of complications. Specific case report forms were used for this purpose.

Conclusions

Our report describes in detail the high rates of PCI success and low rates of PCI complications observed in the PCI arm of the OAT. Mechanisms of PCI failure in these subacute occlusions resemble those in chronic occlusions. Analysis of long-term outcomes comparing cohorts with PCI success versus failure and cohorts with PCI success versus MED (as-treated) does not suggest that higher rates of PCI success or protocol compliance would have altered the findings of the primary intention-to-treat analysis. Finally, we found no signal of late benefit attributable

to routine PCI for persistent IRA occlusion in a landmark analysis designed to discount the potential influence of procedural hazard.

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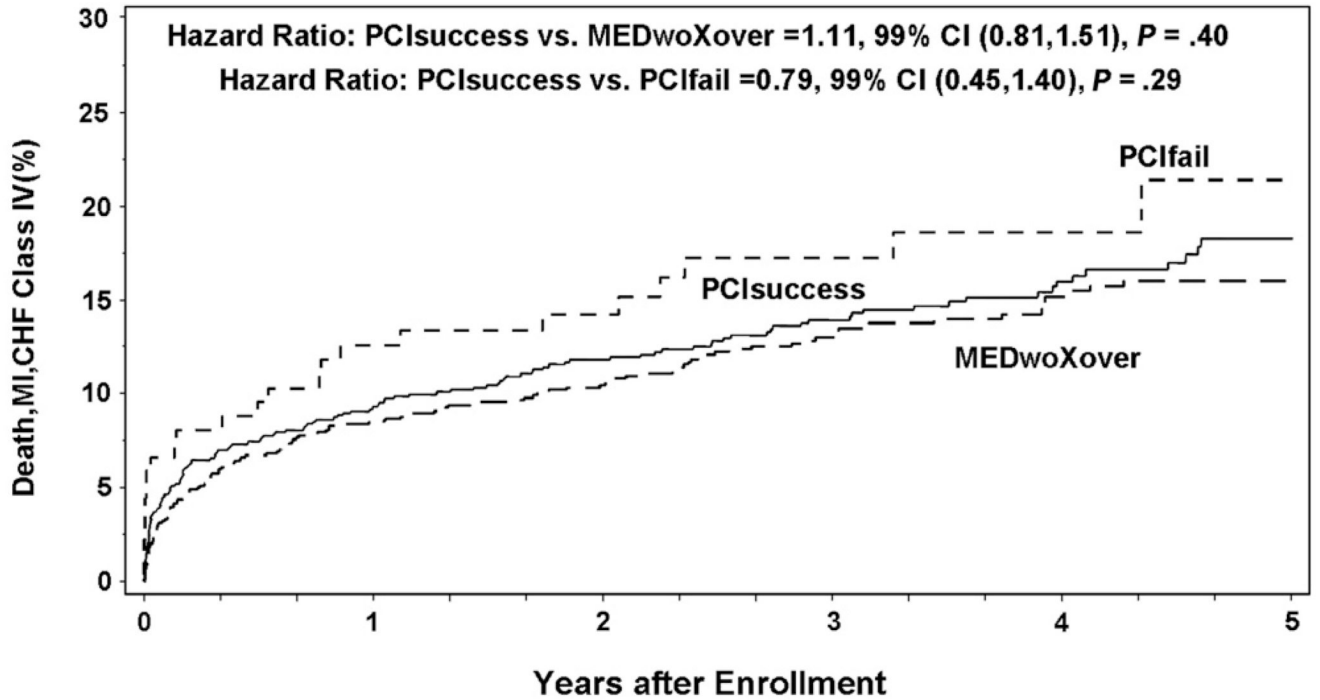
Figure 1.
Primary OAT outcome according to PCI success or failure (fail) in PCI-assigned patients, and
for reference, in MED-assigned patients treated without crossover to PCI or coronary artery
bypass graft within 30 days of enrollment (MED); no significant difference in outcomes over
5 years was detected (HR succ vs fail 0.79, 99% CI 0.45–1.40, P = .29; HR succ vs MED 1.11
99% CI 0.81–1.51, P = .40).
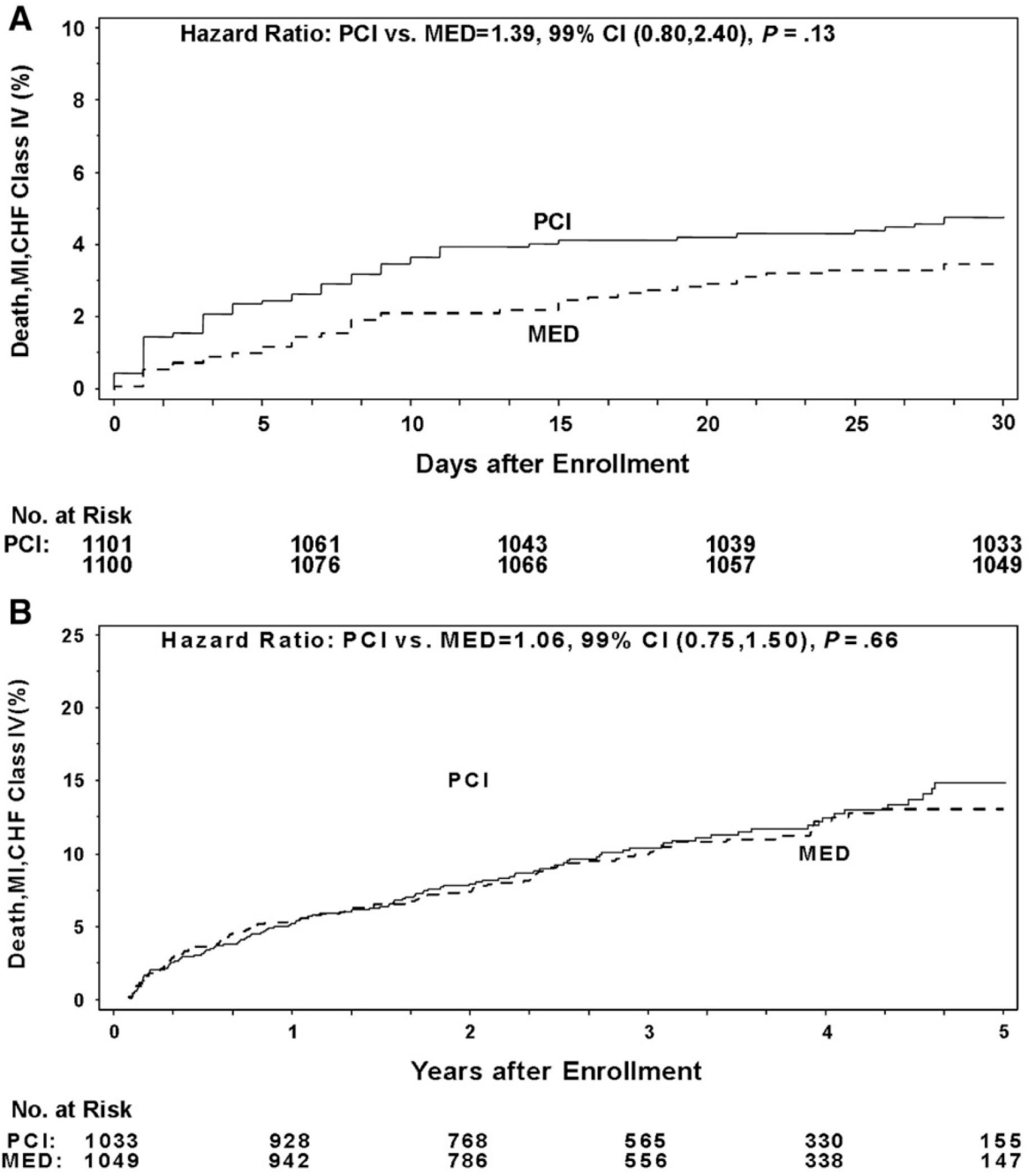
Figure 2.
Landmark analysis of the OAT primary outcome by intention-to-treat (**A**) from enrollment through 30 days and (**B**) after 30 days to 5 years.

Table I

Location and characteristics of qualifying occlusions

	PCI-Assigned patients				MED-Assigned patients			
	All PCI (N = 1093)	LAD (n = 378)	LCX (n = 177)	RCA (n = 538)	All MED (n = 1090)	LAD (n = 406)	LCX (n = 156)	RCA (n = 528)
Proximal segment	999 (91.4)	369 (97.6)	99 (55.9)	531 (98.7)	1017 (93.3)	396 (97.5)	100 (64.1)	521 (98.7)
Reference diameter, mean (SD)	3.2 (0.7)	3.0 (0.7)	3.1 (0.6)	3.3 (0.7)	3.3 (0.7)	3.2 (0.7)	3.1 (0.7)	3.4 (0.8)
Multivessel disease	189 (17.3)	67 (17.7)	45 (25.4)	77 (14.3)	190 (17.4)	67 (16.5)	32 (20.5)	91 (17.2)
TIMI flow	1091	378	176	537	1089	406	155	528
TIMI 0	902 (82.7)	301 (79.6)	146 (82.9)	455 (84.7)	903 (82.9)	317 (78.1)	132 (85.2)	454 (86.0)
TIMI 1	182 (16.7)	72 (19.1)	29 (16.5)	81 (15.1)	184 (16.9)	87 (21.4)	23 (14.8)	74 (14.0)
TIMI 2/3	7 (0.6)	5 (1.3)	1 (0.6)	1 (0.2)	2 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)
Collateral grade	1087	375	175	537	1086	405	154	527
Grade 0	134 (12.3)	61 (16.3)	44 (25.1)	29 (5.4)	117 (10.8)	63 (15.6)	29 (18.8)	25 (4.7)
Grade 1	778 (71.6)	299 (79.7)	115 (65.7)	364 (67.8)	770 (70.9)	317 (78.3)	113 (73.4)	340 (64.5)
Grade 2	175 (16.1)	15 (4.0)	16 (9.1)	144 (26.8)	199 (18.3)	25 (6.2)	12 (7.8)	162 (30.7)
MI to enrollment (d), median (IQR)	8 (5–16)	9 (5–17)	7 (4–14)	9 (5–17)	8 (5–17)	9 (5–17)	6.5 (4–13)	9 (5–18)
LAD segment 12	129 (11.8)	129 (34.1)			142 (13.0)	142 (35.0)		

Values are shown as n (%), unless otherwise specified. Reference diameter, *n* = 953 and 824.

LAD, Left anterior descending artery; *LCX*, left circumflex coronary artery; *RCA*, right coronary artery; *IQR*, interquartile range.

Table II

Percutaneous coronary intervention variables

PCI Attempted within 30 d, n	All 1090		LAD 377		LCX 176		RCA 537		MED 33	
MI to PCI (d), median (IQR)	9	(5–17)	9	(5–17)	7	(4–15)	9	(5.18)	10	(4.22)
Stent attempted	961	(88.2)	341	(90.4)	154	(87.5)	466	(86.8)	31/32	(96.9)
GPI administered,	727	(66.7)	259	(68.9)	106	(60.2)	362	(67.4)	22/32	(68.8)
Stent deployed	938	(86.1)	334	(88.6)	151	(85.8)	453	(84.4)	NA	
Non-IRA PCI	82	(7.5)	23	(6.1)	20	(11.4)	39	(7.3)	0/33	(0.0)
PCI Success *	953	(87.4)	341	(90.4)	153	(86.9)	459	(85.5)	31/32	(96.9)
Stented success	938	(86.1)	334	(88.6)	151	(85.8)	453	(84.4)	NA	

Values are shown as n (%), unless otherwise specified. *GPI*, Glycoprotein IIb/IIIa inhibitor.

*
Site reported result used when core laboratory adjudication not available (n = 9 successful, 4 failed).

Table III

Distribution of angiography data by PCI success status (PCI arm)

Angiographic variable	PCI Success (n = 953)	PCI Fail (n = 137)	No attempt (n = 11)	*P*
Baseline				
TIMI Flow	n = 943			.02
Grade 0	768 (81.4%)	125 (91.2%)	9 (81.8%)	
Grade 1	169 (17.9%)	12 (8.8%)	1 (9.1%)	
Grade 2	5 (0.5%)	0 (0.0%)	0 (0.0%)	
Grade 3	1 (0.1%)	0 (0.0%)	1 (9.1%)	
MLD (mm)[*]	944, 0.0, 0.1	137, 0.0, 0.0	11, 0.1, 0.4	.02
% Diameter stenosis[*]	944, 99.8, 2.1	137, 100.0, 0.0	11, 96.0, 13.3	.01
Collaterals	n = 939			.19
Grade 0	120 (12.8%)	11 (8.0%)	3 (27.3%)	
Grade 1	671 (71.5%)	99 (72.3%)	8 (72.7%)	
Grade 2	148 (15.8%)	27 (19.7%)	0 (0.0%)	
Post-PCI				
TIMI Flow	n = 944			
Grade 0	2 (0.2%)	N/A	N/A	
Grade 1	9 (1.0%)	N/A	N/A	
Grade 2	54 (5.7%)	N/A	N/A	
Grade 3	879 (93.1%)	N/A	N/A	
In-lesion[*]				
MLD (mm)	933, 2.2, 0.5	N/A	N/A	
% Diameter stenosis	941, 29.3, 14.3	N/A	N/A	
In-stent[*]				
MLD (mm)	906, 2.7, 0.5	N/A	N/A	
% Diameter stenosis	914, 14.0, 13.8	N/A	N/A	
Multivessel disease	156/945 = 16.5	29/137 = 21.2	4/11 = 36.4	.18

MLD, Minimum lumen diameter.

[*] Values are shown as n, mean, SD.

Table IV

Early complications and adverse events according to treatment assignment and treatment received

Complication	Treatment assigned (ITT)		Treatment received	
	PCI (n = 1101)	MED (n = 1100)	PCI (n = 1123)	No PCI (n = 1078)
Vascular	5 (4)	1 (0)	5 (4)	1 (0)
Major hemorrhage	8 (3)	1 (0)	9 (3)	0 (0)
CNS	3 (1)	2 (0)	2 (1)	3 (0)
Ventricular arrhythmia	6 (1)	2 (0)	6 (1)	2 (0)
Coronary perforation	4 (4)	1 (1)	5 (5)	0 (0)
Cardiac rupture	2 (1)	2 (0)	2 (1)	2 (0)
Nonfatal MI ≤48 h	8 (6)	2 (0)	10 (6)	0 (0)
Death <48 h	4 (3)	4 (1)[*]	4 (3)	4 (1)[*]
Elevated serum markers[†]	101/1031	30/933	104/1052	27/912

Values in parentheses indicate the number of complications adjudicated as PCI-related by Morbidity and Mortality Classification Committee.

ITT, Intent-to-treat; *CNS*, central nervous system.

[*] Non-IRA PCI.

[†] Site reported; marker elevation alone did not meet protocol prespecified criteria for MI.

Table V

Distribution of baseline characteristics by PCI success status (PCI arm)

	PCI Success (n = 953)	PCI Fail (n = 137)	No attempt (n = 11)	P*
Age, mean (SD)	58.5 (11.0)	58.8 (9.9)	62.8 (13.7)	.74
Male	735 (77.1)	117 (85.4)	7 (63.6)	.03
Days from MI, median (IQR)	8 (5–16)	9 (5–18)	6 (4–10)	.27
Days 7–28 post MI	525 (55.1)	79 (57.7)	5 (45.5)	.57
ST Elevation/new Q/R loss	829 (87.0)	118 (86.1)	10 (90.9)	.78
Post fibrinolysis	192 (20.1)	31/136 (22.8)	4 (36.4)	.47
Killip class ≥2	179/950 (18.8)	39 (28.5)	4 (36.4)	.009
Diabetes	179 (18.8)	22 (16.1)	2 (18.2)	.44
Current smoker	370 (38.8)	53 (38.7)	5 (45.5)	.98
GFR (mL/min), mean (SD)	81.1 (21.4) n = 937	78.8 (20.3) n = 136	68.6 (21.1)	.24
History of CHF	23 (2.4)	4 (2.9)	0 (0.0)	.72
History of PCI	33 (3.5)	16 (11.7)	2 (18.2)	<.001
EF, mean (SD)	n = 946 47.8 (11.2)	45.7 (11.8)	42.4 (10.7)	.04
LAD Target	341 (35.8)	36 (26.3)	6 (54.5)	.03
TIMI 0 flow	768/943 (81.4)	125 (91.2)	9 (81.8)	.005
Reference diameter (mm), mean (SD)	n = 832, 3.1 (0.7)	n = 114, 3.3 (0.9)	n = 7, 3.1 (0.4)	.06
Collateral present	819/939 (87.2)	126 (92.0)	8 (72.7)	.12

Values are shown as n (%), unless otherwise specified.

GFR, Glomerular filtration rate; *CHF*, congestive heart failure; *EF*, ejection fraction.

*Comparison (univariable) of PCI success vs PCI failure.

Table VI

Outcome after PCI success vs failure (life table estimates at 60 m)

	PCI-Assigned patients				MED-Assigned patients			
	PCI Success (n = 953)	PCI Failure (n = 137)	No PCI (n = 11)	All PCI (N = 1101)	MED without PCI of IRA* (n = 1072)	MED with PCI of IRA* (n = 28)	All MED (N = 1100)	P[†]
Class IV HF	4.8	4.3	25.0	4.9	4.1	11.7	4.3	NS
Nonfatal MI	6.6	7.2	16.7	6.8	4.8	3.6	4.7	NS
Death	11.4	12.9	23.8	11.7	12.0	3.6	11.8	NS
Composite	18.3%	21.4%	48.6	18.9	16.0	18.5	16.1	NS

NS, Not significant.

*
PCI of IRA within 30 d and prior to any end point.

[†] *P* value refers to success vs fail, and success vs MED without crossover within 30 d (two 2-way comparisons, both *P*-NS).