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Outcomes of Optimal or "Stent-Like" Balloon Angioplasty in Acute Myocardial Infarction: The CADILLAC Trial

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OBJECTIVES We sought to compare outcomes between patients with acute myocardial infarction (AMI) undergoing percutaneous transluminal coronary angioplasty (PTCA) with an optimal or "stent-like" result versus patients who underwent routine stent placement.

BACKGROUND Recent studies in patients with AMI undergoing stent implantation have suggested that PTCA may no longer be a relevant treatment modality for stent eligible lesions. However, whether routine stent placement is superior or necessary when an optimal PTCA or "stent-like" result is achieved is unknown.

METHODS In the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) trial, 2,082 patients with AMI were randomly assigned to undergo PTCA alone, PTCA + abciximab, stenting alone, or stenting + abciximab. Outcomes were compared in patients achieving an optimal acute PTCA result (residual core laboratory diameter stenosis <30% without significant dissection) versus those assigned to routine stenting.

RESULTS Optimal PTCA was achieved in 40.7% of patients randomized to balloon angioplasty, including 38.5% and 42.7% assigned to PTCA alone and PTCA + abciximab, respectively. Ischemic target vessel revascularization (TVR) at 30 days occurred more frequently after optimal PTCA than routine stenting (5.1% vs. 2.3%, $p = 0.007$). The one-year composite adverse event rate (death, reinfarction, disabling stroke, or TVR) was greater after optimal PTCA than routine stenting (21.9% vs. 13.8%, $p < 0.001$), driven largely by increased rates of ischemic TVR (19.1% vs. 9.1%, $p < 0.001$); no significant differences were present in the rates of death, reinfarction, or disabling stroke between the two groups. Angiographic restenosis also was more common with optimal PTCA than routine stenting (36.2% vs. 22.2%, $p = 0.003$). Even a post-PTCA diameter stenosis of <20% (realized in 12% of patients) did not result in outcomes equivalent to stenting.

CONCLUSIONS Even if an optimal result is achieved after primary PTCA in AMI, early and late outcomes can be further improved with routine stent implantation. (J Am Coll Cardiol 2003;42: 971–7) © 2003 by the American College of Cardiology Foundation

The reduction in restenosis after coronary stent implantation compared with percutaneous transluminal coronary balloon angioplasty (PTCA) has been attributed to the ability of the stent to achieve a larger immediate post-procedure minimal luminal diameter (1–3). Some (4–9), but not all (10–14) studies of elective percutaneous coronary intervention (PCI) have demonstrated equivalent long-term outcomes in patients achieving an optimal or "stent-like" PTCA result compared with a strategy of routine stent implantation, which may result in reduced health care resource consumption and medical costs (15–18). As the underlying culprit plaque in acute myocardial infarction (AMI) is typically soft and modest in severity (19–23), PTCA in this setting might be expected to more frequently result in an optimal result with a lower residual stenosis compared to intervention in patients with stable angina. However, whether the early and late outcomes in AMI

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Abbreviations and Acronyms

AMI = acute myocardial infarction
CADILLAC = Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications
NHLBI = National Heart, Lung, and Blood Institute
PCI = percutaneous coronary intervention
PTCA = percutaneous transluminal coronary angioplasty
TIMI = Thrombolysis In Myocardial Infarction
TVR = target vessel revascularization

patients achieving an optimal PTCA result are comparable to those undergoing routine stent implantation is unknown.

The Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) trial was a large-scale multicenter, prospective, randomized trial designed to determine the optimal reperfusion strategy in patients with evolving AMI (24). The purpose of this present analysis is to determine the frequency of achieving an optimal PTCA result in AMI, and whether the long-term outcomes after optimal PTCA are similar and cost-effective compared with a routine stent strategy.

METHODS

Study population and study protocol. The details of the CADILLAC protocol have been previously reported (24). In brief, 2,082 patients of any age with AMI within 12 h of symptom onset at 82 international centers were randomized to undergo PTCA alone, PTCA + abciximab, stenting alone with the MultiLink or MultiLink Duet stent (Guidant, Santa Clara, California), or stenting + abciximab. Patients with cardiogenic shock, current administration of thrombolytic therapy, stroke within two years, or any permanent residual neurologic defect were excluded. All patients provided written informed consent before enrollment.

Catheterization procedure and concomitant medications. Patients received 324 mg of chewable aspirin, ticlopidine 500 mg or clopidogrel 300 mg, a 5,000-U heparin bolus, and intravenous beta-blockade in the absence of contraindications before catheterization. Left ventriculography and arteriography were performed with ioxoaglate, with randomization of consecutive patients meeting angiographic enrollment criteria (native coronary artery infarct vessel with estimated lesion length ≤64 mm and reference diameter 2.5 to 4.0 mm).

Among patients randomized to PTCA (with or without abciximab), crossover to stenting (bail-out) was permitted for a visually estimated residual stenosis of >50% or dissection ≥ National Heart, Lung, and Blood Institute (NHLBI) type C. However, before stent implantation in PTCA assigned patients, prolonged balloon inflations of at least 5 min were mandated (with an autoperfusion balloon recommended), as was the use of slightly oversized balloons.

Data collection, definitions, and statistical analysis. Independent study monitors verified 100% of case report form data on-site, and all primary end point events were adjudicated by an independent committee blinded to randomization allocation. Core laboratory angiographic analysis was performed as previously described (25). Follow-up angiography at seven months was completed in 656 (72.9%) of 900 pre-specified eligible patients and was evaluable in 628 patients.

The primary end point was a composite of death from any cause, reinfarction, repeated percutaneous intervention or surgical revascularization of the target vessel as a result of ischemia, or disabling stroke. For the present analysis, an optimal or "stent-like" PTCA result was defined as a residual core angiographic laboratory-determined diameter stenosis <30% with dissection ≤ NHLBI type A and final Thrombolyis In Myocardial Infarction (TIMI) grade 3 flow obtained by balloon angioplasty only, a definition similar to that employed in previous analyses of optimal PTCA results (4). Other definitions were as previously described (24). Procedural and clinical outcomes of patients achieving optimal PTCA were compared with those of all patients assigned to stenting.

For the economic analysis, medical care costs were assessed for all U.S. patients in the study cohort using

Table 1. Demographic Features and Procedural Outcomes

	Optimal PTCA (n = 415)	Stent (n = 1,036)	p Value
Age (yrs)	61 (52–69)*	59 (51–68)	0.23
Age >70 yrs	19.8%	20.7%	0.70
Male gender	74.7%	73.3%	0.60
Current smoker	40.0%	43.5%	0.24
Diabetes mellitus	18.3%	17.8%	0.82
Hypertension	48.0%	47.9%	1.00
Hypercholesterolemia	37.6%	37.5%	1.00
Prior myocardial infarction	14.9%	12.5%	0.23
Index LVEF % (operator defined)	50 (40–58)	50 (40–58)	0.86
Multivessel disease	45.8%	49.6%	0.20
Killip class I	87.4%	88.7%	0.53
ST-segment elevation or LBBB	85.1%	87.6%	0.25
Symptom onset to ER arrival (h)	1.8 (1.0–3.0)	1.9 (1.0–3.6)	0.27
ER arrival to balloon inflation (h)	2.0 (1.5–2.8)	2.0 (1.5–2.7)	0.81
Infarct-related artery			
Left anterior descending	37.6%	36.1%	0.63
Left circumflex	20.5%	18.3%	0.37
Right	41.9%	45.6%	0.22
Abciximab administered	53.3%	52.6%	0.86
Maximal device size (mm)	3.3 (3.0–3.5)	3.5 (3.0–3.5)	0.02
Maximal pressure (atm)	9 (8–12)	14 (13–16)	<0.0001

*Data are presented as median, with interquartile range in parentheses.

ER = emergency room; LBBB = left bundle-branch block; LVEF = left ventricular ejection fraction; PTCA = percutaneous transluminal coronary angioplasty.

Table 2. Core Laboratory Angiographic Analysis

	Optimal PTCA (n = 415)	Stent (n = 1,036)	p Value
TIMI flow pre			
0–1	66.0%	67.0%	0.72
2	9.7%	10.3%	0.77
3	24.3%	22.7%	0.54
TIMI flow final			
0–1	0%	1.5%	0.008
2	0%	2.8%	< 0.0001
3	100%	95.7%	< 0.0001
Angiographic subset			
n	130	325	
Reference diameter pre (mm)	2.8 (2.6–3.2)*	3.0 (2.6–3.3)	< 0.001
Minimal luminal diameter pre (mm)	0 (0–0.7)	0 (0–0.8)	0.62
Minimal luminal diameter post (mm)	2.2 (2.0–2.5)	2.4 (2.1–2.7)	< 0.001
Minimal luminal diameter at 7 months (mm)	1.6 (1.2–2.1)	2.0 (1.6–2.4)	< 0.001
Diameter stenosis pre (%)	100	100	0.53
Diameter stenosis post (%)	22.2	11.9	< 0.0001
Diameter stenosis at 7 months (%)	39.0	29.5	< 0.0001
Restenosis (%)	36.2	22.2	0.003
Infarct artery reocclusion (%)	10.0	5.8	0.15
Left ventricular ejection fraction (%)			
Index procedure	56.83 (48.08–63.65)	55.99 (46.99–63.80)	0.35
Follow-up	61.48 (53.87–68.66)	60.14 (51.56–68.70)	0.28
Infarct zone regional wall motion (SD/chord)			
Index procedure	−1.22 (−1.61 to −0.84)	−1.34 (−1.67 to −0.82)	0.13
Follow-up	−0.77 (−1.23 to −0.33)	−0.80 (−1.30 to −0.32)	0.63

*Data are expressed as median, with interquartile range in parentheses.
PTCA = percutaneous transluminal coronary angioplasty; SD = standard deviation; TIMI = Thrombolysis In Myocardial Infarction.

previously described methodology (17). Detailed resource utilization data were recorded for all revascularization procedures, and procedural costs were based on measured resource utilization and 2001 unit costs. Non-procedural hospital costs were estimated by converting hospital charges to costs according to hospital and cost-center specific cost-to-charge ratios. Costs for inpatient and outpatient physician services were calculated using the 2001 Medicare fee schedule for Massachusetts. Stent- and abciximab-related costs from the index procedure were included in the economic formulas. All repeat revascularization procedures were reviewed by an independent clinical events committee blinded to treatment assignment to determine whether they were prompted by symptoms, ischemia, or protocol-driven angiography. In the patient cohort assigned to follow-up angiography, repeat cardiac catheterization, associated hospital costs, and any related revascularization procedures that were judged to have been protocol-induced rather than clinically driven were excluded from the economic analysis. The incremental cost-effectiveness ratio for stenting compared with optimal PTCA was calculated by dividing the mean one-year cost difference by the difference in one-year repeat revascularization rates between the two groups, as previously described (17,26).

Categorical variables were compared by Fisher exact test. Continuous variables are presented as median (interquartile range) or mean ± standard deviation and were compared by the Wilcoxon two-sample test. Time to event data were displayed as Kaplan-Meier curves and compared by the log-rank test. All analyses were by intention to treat, and all p values are two-sided. Significance was established at $p < 0.05$. Adjustments for multiple comparisons were not performed.

RESULTS

Patient population and baseline characteristics. A total of 1,046 patients were randomized to PTCA with or without abciximab, 168 (16%) of whom required a stent for unacceptable results. Of the remaining 878 patients, core laboratory angiographic analysis was complete in 855, 415 of whom had an optimal PTCA result. Optimal PTCA was thus achieved in 415 (40.7%) of 1,023 evaluable PTCA patients, including 38.5% and 42.7% assigned to PTCA alone and PTCA + abciximab, respectively ($p = 0.17$).

Patients in whom optimal PTCA was achieved and those assigned to routine stent implantation were well-matched with respect to baseline clinical characteristics (Table 1). Stents were implanted in 97.9% of patients assigned to stenting, and by definition in 0% of optimal PTCA patients. Infarct artery distribution and abciximab use were similar in the two groups (Table 1). Maximum device size and maximum balloon pressures were higher in the routine stent group.

Angiographic results. Core laboratory angiographic analysis appears in Table 2. The TIMI-3 flow rates were similar at baseline. By definition, all patients with optimal PTCA

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Table 3. Early and Late Clinical Outcomes

	Optimal PTCA (n = 415)	Stent (n = 1,036)	p Value
30-day event rates (%)			
Composite end point	6.8	5.0	0.20
Death	1.7	2.4	0.39
Disabling stroke	0	0.2	0.37
Reinfarction	0.2	0.9	0.19
Ischemic target vessel revascularization	5.1	2.3	0.007
Subacute thrombosis	1.0	0.5	0.29
1-year event rates (%)			
Composite end point	21.9	13.8	<0.0002
Death	3.2	4.2	0.28
Disabling stroke	0.3	0.7	0.31
Reinfarction	2.2	2.2	0.99
Ischemic target vessel revascularization	19.1	9.1	<0.0001

Composite end point = death, disabling stroke, reinfarction, or ischemic target vessel revascularization; PTCA = percutaneous transluminal coronary angioplasty.

achieved TIMI-3 flow compared to 95.7% of routine stent patients. Despite similar baseline quantitative measures, patients assigned to stenting had a significantly lower diameter stenosis post procedure and at follow-up, with a correspondingly marked reduction in binary angiographic restenosis. Myocardial recovery and infarct artery reocclusion were similar in both groups.

Clinical outcomes. At 30 days, no differences were noted between optimal PTCA and routine stenting with respect to the primary composite end point of death, reinfarction, ischemic target vessel revascularization (TVR), or disabling stroke (Table 3). The individual 30-day rates of mortality, disabling stroke, reinfarction, and subacute thrombosis were also comparable between the two groups, though recurrent ischemia necessitating repeat TVR was twice as common after optimal PTCA compared with routine stent implantation (Table 3). An optimal PTCA result did not provide freedom from subacute thrombosis.

At one year, event-free survival was significantly greater in patients assigned to routine stenting than in those achieving optimal PTCA, driven primarily by greater freedom from ischemic TVR in patients randomized to stenting (Table 3). Rates of death, disabling stroke, and reinfarction were similar among the two groups. Early and late outcomes among patients achieving optimal PTCA were unaffected by abciximab randomization (Fig. 1).

The results of optimal PTCA were inferior to those of routine stent implantation for most relevant clinical and angiographic subgroups examined, except in very large vessels (Fig. 2); no patient or lesion subsets were identified in which the late outcomes of optimal PTCA were superior to stent implantation. Notably, restricting the definition of optimal PTCA to require a core laboratory diameter stenosis <20% (present in 12.3% of patients) did not significantly improve the absolute or relative late prognosis compared with routine stenting (Fig. 2).

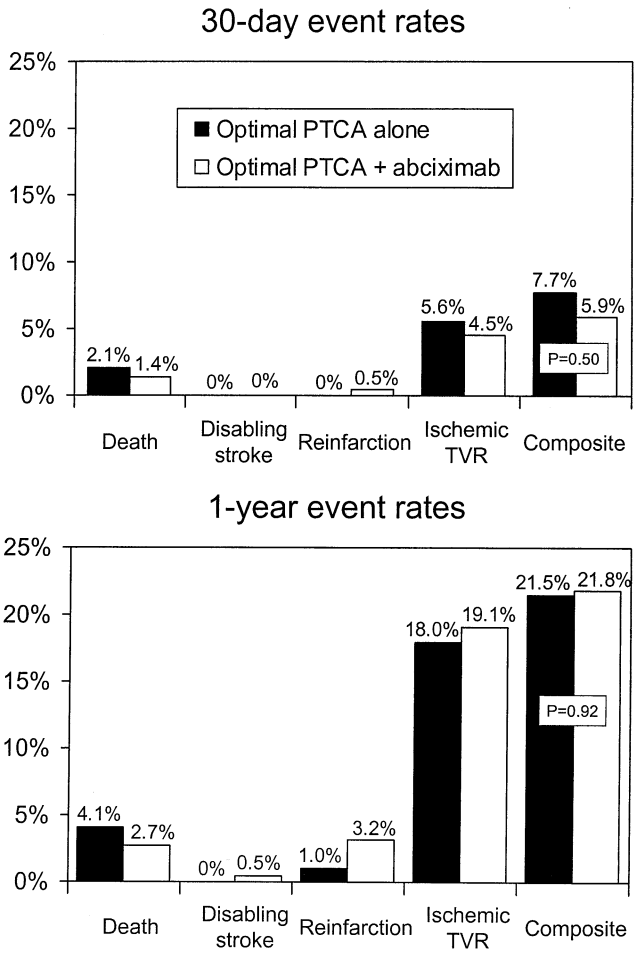

Figure 1. Individual and composite adverse event rates at 30 days **(upper graph)** and 1 year **(lower graph)** in patients achieving optimal percutaneous transluminal coronary angioplasty (PTCA) results randomized to pre-procedural abciximab administration **(white bars)** versus no pre-procedural abciximab. The p values for all two-way comparisons in both graphs are non-significant. TVR = target vessel revascularization.

Economic analysis. Routine stenting increased hospital costs by a mean of $2,519 per patient (Table 4). Over one year, stent patients required significantly fewer hospital admissions, hospital days, and repeat revascularization procedures. As a result, follow-up costs were a mean of $1,635 less per patient in the routine stent group, resulting in aggregate one-year costs that were $883 higher in the stent group (p = 0.20). The mean cost-effectiveness ratio for routine stenting versus optimal PTCA was thus $6,104 per repeat revascularization procedure avoided.

DISCUSSION

Routine stent implantation in patients undergoing mechanical reperfusion therapy for AMI has been clearly shown to result in reduced rates of angiographic restenosis and subsequent need for TVR (24,27–33). However, stent implantation may occasionally have undesirable consequences, including "jailing" of side branches and refractory in-stent restenosis (34–38). Furthermore, the additional catheteriza-

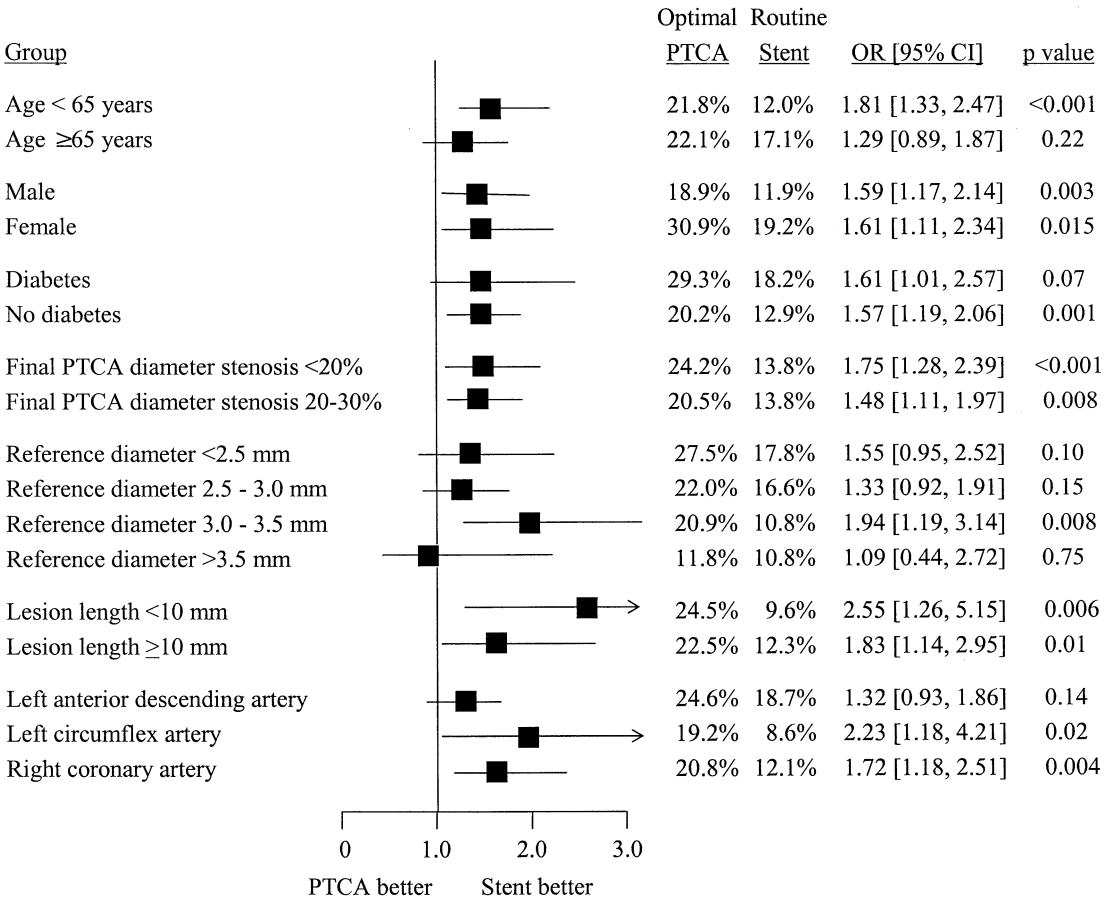

Figure 2. Subgroup analysis for the one-year composite end point of death, disabling stroke, reinfarction, or ischemic target vessel revascularization, comparing patients achieving an optimal percutaneous transluminal coronary angioplasty (PTCA) result (n = 415) with all patients randomized to stent implantation (n = 1,036), displayed as hazard ratios **(black boxes)** with 95% confidence intervals (CI) **(horizontal limit lines).** OR = odds ratio.

tion laboratory and index hospitalization costs of routine stent use are not trivial (17). For these reasons, a "balloon only" approach might be desirable in selected patients. In the large multicenter CADILLAC trial, however, stenting compared with PTCA by intention to treat analysis resulted in improved outcomes in all examined pre-specified clinical subsets (24). Whether the early and late outcomes of patients achieving optimal or "stent-like" PTCA are equivalent to those undergoing routine stenting (in accordance with the "bigger is better" dictum [39,40]) has not been comprehensively examined in an AMI population, though studies in the elective setting have suggested that such a strategy may have merit (4–9).

The principal finding of the present analysis is that even the achievement of an optimal PTCA result during primary PCI for AMI, as defined by strict quantitative core laboratory criteria, did not result in equivalent outcomes compared with a routine stent strategy. Of note, using contemporary techniques (including prolonged balloon inflations and the luxury of balloon oversizing afforded by the availability of stents to manage severe dissection), an optimal PTCA result could be realized in a relatively large percentage (40.7%) of

Table 4. Economic Analysis

	Optimal PTCA (n = 329)	Stent (n = 846)	p Value
Index PCI cost	$3,014 ± 846*	$4,652 ± 1,283	< 0.0001
Total index length of stay (days)	4.76 ± 2.16	5.17 ± 3.42	0.04
Total index hospital costs	$11,386 ± 4,537	$13,905 ± 5,506	< 0.0001
Repeat hospitalization (%)	66	48	0.001
Rehospitalization days (n per 100 patients)	238 ± 447	184 ± 418	0.05
Patients with repeat revascularization (%)	26	18	0.001
Total follow-up costs discharge to one year	$6,589 ± 10,173	$4,954 ± 8,106	0.004
Total one-year costs	$17,976 ± 11,416	$18,859 ± 10,280	0.200

*Data are expressed as mean ± SD.
PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty.

PTCA patients in this trial. However, even those patients in CADILLAC with optimal acute PTCA results did not have equivalent short- and long-term outcomes compared with stenting; optimal PTCA patients still had higher rates of recurrent ischemia necessitating TVR at 30 days, and late restenosis necessitating TVR between 30 days and one year, independent of randomization to abciximab. Optimal PTCA did not match the late results of routine stenting even when a post-PTCA diameter stenosis <20% by quantitative angiography was achieved (equivalent to a visually estimated residual stenosis of 0% to 10%). Economic analysis demonstrated acceptable cost-effectiveness for routine stenting compared with optimal PTCA. Thus, routine stent placement should be the default therapy in primary PCI for AMI in most patients.

The relative benefits of a routine stent strategy compared with optimal PTCA were independent of gender, diabetes, and lesion length and were present in young patients, intermediate diameter vessels, and left circumflex and right coronary artery infarcts. Trends were also present for improved outcomes of routine stenting compared with optimal PTCA in the elderly, small vessels, and in infarcts involving the left anterior descending artery. Only in large vessels (reference vessel diameter >3.5 mm by quantitative coronary angiography, likely equivalent to >3.8 mm by visual estimate) did the late outcomes of optimal PTCA match those of routine stenting. If an optimal balloon result is obtained, PTCA may therefore be an attractive alternative to stenting in large vessels, especially if other features are present that weigh against stent implantation, such as proximity of a large side branch that would be jailed.

Abciximab as an adjunct to PTCA or stenting provided short-term clinical benefits in the CADILLAC trial, with a reduction in 30-day ischemic TVR and subacute vessel closure for both stent and PTCA patients, but had no impact upon long-term mortality or ischemic TVR. When abciximab utility was examined in patients achieving optimal PTCA in this analysis, however, no significant early or late benefits were seen, most likely because the presence of an optimal angiographic PTCA result (low residual stenosis without dissection) produced excellent short-term clinical event rates, with a low rate of subacute thrombosis and recurrent ischemia even without the glycoprotein IIb/IIIa inhibitor.

In terms of cost-effectiveness, reduced initial hospitalization costs with optimal PTCA were offset by the increased expense of more frequent revascularization procedures during the follow-up period, resulting in a cost-effectiveness ratio for routine stenting versus optimal PTCA of $6,104 per repeat revascularization procedure avoided over the one-year study period. This is similar to the cost-effectiveness ratios seen for elective stenting versus PTCA (approximately $10,000 per repeat revascularization avoided) and brachytherapy for diffuse in-stent restenosis (approximately $5,000 per repeat revascularization avoided) (3,26).

Several limitations of this study should be noted. First, this retrospective analysis was not pre-specified in the original trial design and thus should be viewed as hypothesis-generating rather than definitive. The optimal study design would be a prospective trial in which patients with AMI achieving stent-like PTCA results are then randomized to stent versus no stent. Such a study, however, is not likely to be performed, and the present analysis is the largest investigation to date examining the benefits of optimal PTCA relative to routine stent implantation in AMI. Second, in the present intention to treat analysis, the routine stent arm included patients in whom optimal PTCA after pre-dilation was not achieved, and even some patients in whom a stent was not implanted. These occurrences, however, would have biased the results against the routine stent arm, and thus make the conclusions favoring routine stent implantation even stronger. Third, the definition of an optimal PTCA (diameter stenosis <30% by quantitative coronary analysis, equivalent to a visually estimated residual stenosis of <10% to 20%) is one historically used by core angiographic laboratories to define optimal PTCA (4,25), and resulted in 40.7% of PTCA patients in this trial meeting this criterion of an optimal result. Even when a stricter definition of optimal PTCA was examined (core laboratory diameter stenosis <20%, obtainable in only 12.3% of PTCA patients), routine stenting still provided superior early and late outcomes. Intravascular ultrasound or physiologic lesion assessment, though infrequently performed during AMI intervention, may have better discriminatory power than angiography to define an optimal PTCA result. Fourth, by definition, final TIMI-3 flow was more frequently present in optimal PTCA than routine stent patients (100% vs. 95.7%, respectively, $p < 0.0001$). Although this did not translate into significantly greater mortality among stented patients in this analysis, a larger study population would be required to exclude this possibility. Finally, patients in cardiogenic shock and saphenous vein graft culprit vessels were excluded from randomization in CADILLAC; whether these observations apply to these subsets, or to patients undergoing elective PTCA, cannot be stated with certainty.

In conclusion, when compared with "optimal" balloon angioplasty in patients undergoing primary PCI for AMI, routine stent implantation can be expected to further reduce restenosis and enhance long-term freedom from repeat hospitalization and revascularization.

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