

10-Year Follow-Up of a Prospective Randomized Trial Comparing Bare-Metal Stenting With Internal Mammary Artery Grafting for Proximal, Isolated De Novo Left Anterior Coronary Artery Stenosis

The SIMA (Stenting versus Internal Mammary Artery grafting) Trial

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Objectives

This study was designed to compare the long-term clinical outcome of coronary artery bypass grafting (CABG) with intracoronary stenting of patients with isolated proximal left anterior descending coronary artery.

Background

Although numerous trials have compared coronary angioplasty with bypass surgery, none assessed the clinical evaluation in the long term.

Methods

We evaluated the 10-year clinical outcome in the SIMA (Stent versus Internal Mammary Artery grafting) trial. Patients were randomly assigned to stent implantation versus CABG.

Results

Of 123 randomized patients, 59 underwent CABG and 62 received a stent (2 patients were excluded). Follow-up after 10 years was obtained for 98% of the randomized patients. Twenty-six patients (42%) in the percutaneous coronary intervention group and 10 patients (17%) in the CABG group reached an end point ($p < 0.001$). This difference was due to a higher need for additional revascularization. The incidences of death and myocardial infarction were identical at 10%. Progression of the disease requiring additional revascularization was rare (5%) and was similar for the 2 groups. Stent thrombosis occurred in 2 patients (3%). Angina functional class showed no significant differences between the 2 groups.

Conclusions

Both stent implantation and CABG are safe and highly effective in relieving symptoms in patients with isolated, proximal left anterior descending coronary artery stenosis. Stenting with bare-metal stents is associated with a higher need for repeat interventions. The long-term prognosis for these patients is excellent with either mode of revascularization. (J Am Coll Cardiol 2008;52:815-7) © 2008 by the American College of Cardiology Foundation

The SIMA (Stent versus Internal Mammary Artery grafting) prospective randomized trial compared clinical outcome of coronary artery bypass grafting (CABG) with percutaneous transluminal coronary angioplasty with bare-

metal stent implantation (percutaneous coronary intervention [PCI]) in patients with isolated proximal left anterior descending (LAD) coronary artery. After 2.4 years of follow-up, overall survival and incidence of myocardial infarction was similar for the 2 strategies (1). Data on long-term follow-up after PCI and internal mammary grafting for single-vessel disease are scarce (2). The SIMA trial data provides a unique opportunity to study these issues in a very homogenous group of patients.

Methods

The SIMA trial enrolled 123 patients (at 6 European sites) to be treated with either stent implantation or CABG for

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Abbreviations and Acronyms

CABG = coronary artery bypass grafting
LAD = left anterior descending
PCI = percutaneous coronary intervention

isolated proximal LAD stenosis and left ventricular ejection fraction >45%. Follow-up was conducted until all patients had reached their 10-year follow-up.

The primary composite end point was all causes of death, myocardial infarction, and the need for additional revascularization. A secondary end point was

angina functional class. These end points were evaluated at 2 and 10 years.

During the first 6 months after the procedure, patients were seen by the referring physician, who obtained the history and performed a physical examination. Noninvasive assessment was performed with a yearly stress test or cardiac scintigraphy. Additional revascularization was left to the discretion of the treating cardiologist in patients with symptomatic or silent ischemia.

Statistical analysis. All analyses were made according to the intention-to-treat principle. Continuous variables were expressed as mean ± SD and discrete variables as counts and percentage. The event-free survival was estimated by the Kaplan-Meier method and compared by a log-rank test. Statistical significance was assigned at the $p < 0.05$ level. Only the most serious adverse event per patient was reported.

Results

A total of 123 patients met the inclusion criteria, but 2 patients were excluded. Thus, 121 patients were finally included. Baseline clinical and angiographic characteristics of both groups were similar. At 1 month there was no difference, with 4% of adverse events in the CABG group

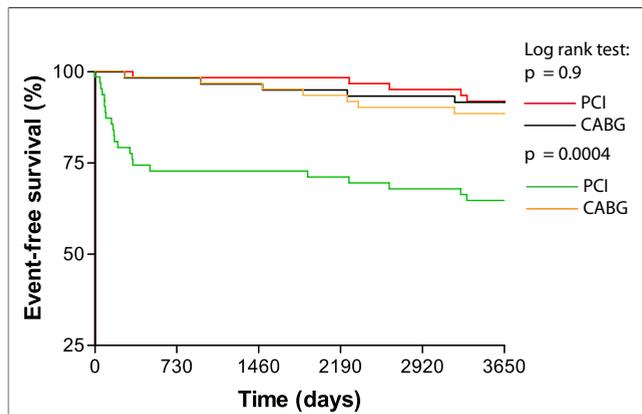


Figure 1 Event-Free Survival Curves

Event-free survival curves for death and myocardial infarction for percutaneous coronary intervention (PCI) (red) and coronary artery bypass grafting (CABG) (black) ($p = 0.9$) and event-free survival curves for death, myocardial infarction, and additional revascularization for PCI (green) and CABG (yellow) ($p < 0.0004$).

Table 1 Adverse Events at 10 Years

	Stent (n = 62)	CABG (n = 59)	p Value
Death	5	4	0.4
Cardiac death	2	1	
Noncardiac death	3	3	
Q-wave MI	0	1	0.9
Non-Q-wave MI	3	2	
TLR	13	0	<0.0001
TVR	2	0	
Non-LAD PTCA	3	3	
Any event	26 (42%)	10 (17%)	<0.0001

CABG = coronary artery bypass grafting; LAD = left anterior descending; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; TLR = target lesion revascularization; TVR = target vessel revascularization.

versus 7% in the PCI group ($p = NS$). At 10 years, a primary end point was reached more frequently in the PCI group than in the CABG group (Fig. 1). Mortality and myocardial infarction rates were not statistically different between the 2 groups (Fig. 1). Five patients died after PCI (8%) and 4 patients after CABG (7%). The cause of death was cardiac in 2 patients after PCI and in 1 patient after CABG. Myocardial infarction (including those of the periprocedural period) occurred in 3 patients in both groups (4%). Stent thrombosis occurred in 2 patients (3%), 1 acute and 1 late; both patients suffered fatal acute myocardial infarction.

Significantly more patients assigned to PTCA required additional revascularization (18 patients [30%] vs. 3 patients [5%]). Revascularization of the LAD was required in 15 patients in the PCI group (25%) compared with none in the CABG group ($p < 0.001$). Finally, 8 patients from the PCI group underwent CABG as an additional revascularization procedure. The incidence of non-LAD revascularization was similar, with 3 patients in both groups (5%) (Table 1). At 10 years, most of the patients in both groups were asymptomatic (93%) or suffered mild angina (7%). A majority of patients received antiplatelet therapy (94% PCI and 96% CABG). Rates of lipid-lowering therapy increased gradually from 24% at 2 years to 89% (88% PCI and 91% CABG) at 10 years. Beta-blockers, angiotensin-converting enzyme inhibitors, and calcium antagonists were given to more than 50% of the patients without differences between the 2 groups. Treatment varied significantly during follow-up.

Discussion

This study provides information on long-term results for 2 revascularization strategies and disease progression in a very homogenous group of patients. The data confirm that the only difference between stenting and left internal mammary artery grafting is in the need for additional revascularization early after the intervention. The relatively high incidence of restenosis and target lesion revascularization is consistent with isolated LAD artery

stenosis (3,4). It is remarkable that no patients randomized to CABG required a second revascularization of the LAD. Our study results confirm the excellent outcome after CABG using this type of graft, which has been shown to remain patent in more than 95% of patients at 5 years (5). The PCI was followed by a higher rate of reintervention. The use of drug-eluting stents might minimize this difference between percutaneous and surgical strategies (6). There are no prospective controlled data comparing proximal LAD stenting with drug-eluting stents with CABG, but in 1 matched cohort observation, there was a surprisingly high incidence of reintervention after drug-eluting stent implantation (7). Furthermore, the incidence and impact of very late drug-eluting stent thrombosis remains unknown and makes it difficult to draw conclusions on whether long-term results with drug-eluting stents would compare favorably to the outcome in our study.

The SIMA trial long-term data provide valuable information about disease progression in single-vessel disease receiving secondary medical prevention with antiplatelet agents and statins. The use of statins increased dramatically from <30% to >90% at 10 years. There is a strikingly low incidence of clinical adverse events attributable to disease progression, as only 5% of our patients required additional non-LAD revascularization. This is important information because use of mammary grafting is often delayed in young patients because of the feared need for further operations. **Study limitations.** Our study describes a small cohort of highly selected patients; therefore, conclusions should not

be applied to other types of lesions and patients. Stents used in the SIMA study were first-generation bare-metal stents.

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Key Words: CABG ■ stenting ■ proximal LAD stenosis.