# Minimally invasive coronary artery bypass grafting versus percutaneous transluminal coronary angioplasty with stenting in isolated high-grade stenosis of the proximal left anterior descending coronary artery: Six months' angiographic and clinical follow-up of a prospective randomized study

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**Objective:** We sought to compare minimally invasive coronary artery bypass grafting (surgical intervention) with percutaneous transluminal coronary angioplasty with primary stenting (stenting) in patients having an isolated high-grade stenosis (American College of Cardiology/American Heart Association classification type B2 or C) of the proximal left anterior descending coronary artery. At 6 months, both procedures were compared on the basis of quantitative angiography and clinical outcome.

**Methods:** Both treatments were compared in a single-center, prospective, randomized study. The primary end point of this study was quantitative angiographic outcome at 6 months. The secondary end point was 6-month clinical outcome. Statistical analysis was performed in accordance with the intention-to-treat principle.

**Results:** From March 1997 to September 1999, patients with angina pectoris caused by an isolated high-grade stenosis of the proximal left anterior descending coronary artery were randomly assigned to surgical intervention (n = 51) or stenting (n = 51). At 6 months, quantitative coronary angiography showed an anastomotic stenosis rate of 4% after surgical intervention and a restenosis rate of 29% after stenting ($P < .001$). Periprocedural events did not significantly differ between surgical intervention and stenting. After surgical intervention, 2 patients died; no patients died after stenting. After 6 months, no significant difference was found for major adverse cardiac or cerebral events and need for repeat target vessel revascularization. After 6 months, return of angina pectoris, physical work capacity, and use of antianginal drugs did not significantly differ between treatments.

**Conclusions:** After 6 months, surgical intervention had a significantly better angiographic outcome than stenting in patients with an isolated high-grade stenosis of the proximal left anterior descending coronary artery. Clinical outcome did not significantly differ between treatments.

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Patients with stenosis of the proximal left anterior descending coronary artery (LAD) of at least 70% have a significantly longer adjusted 3-year survival with conventional coronary artery bypass grafting (CABG) than with percutaneous transluminal coronary angioplasty (PTCA).[1] Reported patency rates after PTCA with stenting of a severe type B2 or C lesion of the proximal LAD are almost 74% to 76% at 6 months' follow-up.[2-4] In contrast, reported patency rates after minimally invasive coronary artery bypass grafting (MICAB) for this lesion are almost 95% to 97%.[5,6] No randomized prospective trials have been reported that compared these 2 revascularization modalities for these type B2 or C lesions of the proximal LAD in specific. Therefore we compared, in a single-center, prospective, randomized clinical trial, MICAB with PTCA with primary stenting for isolated type B2 or C lesions of the proximal LAD.

We present the 6-month angiographic and clinical outcome of this long-term ongoing trial.

## Patients and Methods

### Study Design

Patients with chronic stable angina pectoris of Canadian Cardiovascular Society (CCS) class 2 or greater caused by an isolated type B2 or C lesion of the proximal LAD were selected.[2] Patients had to be eligible for both MICAB and PTCA with primary stenting by unanimous forum decision of cardiologists and cardiac surgeons. Patients with overt congestive heart failure, previous CABG or PTCA procedures, previous myocardial infarction or creatine kinase MB (CK-MB) increase of twice the normal range in the last 2 weeks, congenital heart disease, history of cerebrovascular accident, or need for a concomitant operation were excluded. Before inclusion, the patient provided written informed consent. Included patients were randomly assigned to surgical intervention or stenting. All patients were followed up for 6 months up to their preplanned coronary angiography.

This study was approved by the Ethics Committee of the University Hospital Groningen. Cordis Europe did not participate in the conduct of this study.

### Surgical Technique

MICAB was performed through a small left anterior thoracotomy without cardiopulmonary bypass, as previously described in detail.[7] In short, the left internal thoracic artery (LITA) was harvested under direct vision. The LITA-LAD anastomosis was made during heparinization (activated clotting time of longer than 300 seconds) on the beating heart by using a running 8-0 Prolene suture (Ethicon, Inc, Somerville, NJ) with a mechanical coronary stabilizer (Cardio Thoracic Systems, Inc, Cupertino, Calif) and temporary occlusion of the LAD with a proximal snare. No protamine was given at the end of the procedure. All patients received 100 mg of aspirin daily starting on postoperative day 1.

### PTCA With Stenting Technique

A coronary guiding catheter of 6F to 8F was used to access the coronary arteries through the femoral, brachial, or radial approach. Predilatation of the target lesion was performed with a matched-size or undersized monorail-type or over-the-wire balloon angioplasty catheter. The most optimal stent was implanted at the target site, covering the entire lesion, as well as any proximal or distal intimal dissection. A narrowing of 0% by visual estimation or 20% by quantitative coronary angiography (QCA) was the goal.[2] All patients were pretreated with 500 to 1000 mg of aspirin 24 hours before PTCA with stenting. A bolus of 10,000 to 15,000 IU of heparin was administered intravenously after sheath insertion (activated clotting time of longer than 300 seconds). No protamine was given at the end of the procedure. All patients received 100 mg of aspirin daily and 250 mg of ticlopidin daily from the day of stent implantation until 1 month after the procedure. We used no Gp2b3a receptor blockers.

### Angiographic Analysis

Six months after the initial procedure, a QCA (CAAS, Pie-Medical, Maastricht, The Netherlands) was performed. From 2 orthogonal views, the percentage stenosis diameter was calculated as a mean. Successful revascularization in the MICAB group was defined as a percentage stenosis diameter of the anastomosis of less than 50% of the mid-LITA diameter and in the stent group as a percentage stenosis diameter in the stented segment of less than 50% of the reference diameter of the LAD.[2] The quality of the revascularization of the target vessel was graded as "no abnormalities or small irregularities," "nonsignificant stenosis" (20%-50% luminal stenosis), or "stenotic" ($\geq$50% luminal stenosis).

### End Points and Definitions

The primary end point of the present study was the 6-month angiographic follow-up. Secondary end points were major adverse cardiac or cerebrovascular events (MACCEs), angina pectoris status, use of medication, need for repeat target vessel revascularization, and hospitalization time.

MACCEs were cardiac death, myocardial infarction, and cerebrovascular accident. Cardiac death was defined as death preceded by symptoms of cardiac origin and sudden death not preceded by cardiac symptoms unless clearly of noncardiac origin. Myocardial infarction was diagnosed on the basis of characteristic electrocardiographic findings in combination with elevation of total CK and CK-MB levels. CK levels more than 2 times the upper limit of normal laboratory range and a CK/CK-MB ratio of greater than 10% confirmed the diagnosis of myocardial infarction. Cerebrovascular accident was defined as stroke, transient ischemic attack, or reversible ischemic neurologic deficit if confirmed by a neurologist after computed tomography or magnetic resonance imaging scanning.

Angina pectoris status at 6 months was specified according to the CCS classification. Myocardial ischemia was assessed by means of clinical follow-up and bicycle stress testing at 1 and 6 months after discharge. Myocardial ischemia was defined as typical or atypical anginal pain at rest or during exercise, which was confirmed by the appearance of an ST-segment change of larger than 0.1 mV, T-wave inversion in at least 2 of 12 leads during a bicycle stress test, or both. Repeat target vessel revascularization was performed in the presence of symptoms or signs of ischemia and angiographic restenosis of greater than 50%.

**TABLE 1. Patients' clinical characteristics at baseline**

| | MICAB (n = 51) | PTCA + stent (n = 51) | *P* value |
|---|---|---|---|
| Age (y) | 60 ± 1.6 | 61 ± 1.3 | .73 |
| Female sex | 22% | 25% | .82 |
| Median weight (kg) | 82 | 85 | .27 |
| Hypercholesterolemia | 41% | 45% | .80 |
| Diabetes | 8% | 18% | .23 |
| Hypertension | 16% | 33% | .08 |
| Familial coronary artery disease | 46% | 50% | .84 |
| Past/current smoking | 25/37% | 28/30% | .74 |
| Previous myocardial infarction | 24% | 18% | .63 |
| Duration of angina pectoris (mo) | 16 | 16 | .38 |
| CCS classification | | | .06 |
| Class II | 31% | 27% | |
| Class III | 24% | 46% | |
| Class IV | 45% | 27% | |
| Triple therapy | | | .98 |
| No β/ca-ant/l.a.nit. | 6% | 6% | |
| One of β/ca-ant/l.a.nit | 33% | 31% | |
| At least 2 of β/ca-ant/l.a.nit. | 61% | 63% | |
| Stenosis | 75% ± 1.7% | 75% ± 1.5% | .96 |

β, β-Blocker; *ca-ant*, calcium antagonist; *l.a.nit.*, long-acting nitrate.

### Statistical Analysis

This study was powered to evaluate the 3-year event-free survival of the ongoing study. For the evaluation of the angiographic outcome described in this article, an analysis was planned for 100 patients. For this analysis, no formal sample size calculation was performed.

Statistical analysis was performed in accordance with the intention-to-treat principle. In this setting patients were evaluated on the basis of their randomized treatment, irrespective of the treatment actually received. The baseline descriptive statistics for the continuous variables are given as the mean and SEM. For the normally distributed continuous variables, differences between the 2 strategies were evaluated with the Student *t* test. For skewed distributed continuous end points ($P < .05$, Shapiro-Wilk test for normality), the Mann-Whitney *U* test was used. For qualitative parameters (categorical or ordered), frequency counts and percentages of each category were calculated by treatment strategy. The Fisher exact test or $\chi^2$ test was used to evaluate the differences between surgical intervention and stenting.

QCA outcome for both treatments at 6 months' follow-up was evaluated with a $\chi^2$ test. After 6 months' clinical follow-up, the effect of surgical intervention and stenting on the number of sustained MACCEs was evaluated with a survival analysis. Survival was estimated by using the Kaplan-Meier method. By using a log-rank test, the distribution of event-free survival between the 2 treatment strategies was compared. A second survival analysis was performed on MACCEs and repeat target vessel revascularization. All tests were performed to test the (null) hypothesis that no treatment difference were 2-sided. For all analyses, commercially available computer software (Statistical Analysis System version 6.12; SAS Institute, Cary, NC) was used.

## Results

From March 1997 until September 1999, 102 patients were included in this study. Baseline characteristics did not significantly differ (Table 1). Three patients assigned to MICAB underwent PTCA with stenting: 1 because of severe chronic obstructive pulmonary disease (COPD) implicating a high operative risk according to the anesthetist and 2 who finally refused an operation and preferred PTCA with primary stenting. According to the statistical intention-to-treat principle, these patients were analyzed with the surgical intervention group. Six months' follow-up was completed for 100 patients, and after surgical intervention, 2 patients died.

### Surgical Intervention Group

The surgical intervention group consisted of 51 patients, of whom 3 were primarily treated with PTCA and stenting, as explained above. MICAB was performed as planned in all but 1 patient; this operation was converted to a midline sternotomy because of bleeding. Mean length of stay in the hospital was 7 days (range, 1-20 days).

One patient had a myocardial infarction 1 day after the operation because of a stenosis of the anastomosis requiring PTCA with stenting. One patient died 3 days after the operation because of an ongoing inferoposterior myocardial infarction. Autopsy showed a patent graft and anastomosis of the LITA to the LAD, but the right coronary artery was infarcted by an unknown cause; autopsy also revealed a proximal luminal diameter of 40% in the right coronary artery already known from the preoperative angiography but not identified as significantly stenotic. One week after discharge, 1 patient died at home for unknown reasons after an uncomplicated operation and hospitalization period. Return of angina pectoris of CCS class 2 or greater was found in 3 patients, of whom 2 required repeat target vessel revascularization. One patient was treated with a PTCA of the anastomosis. One patient was treated for unstable angina pectoris caused by in-stent restenosis, requiring repeat target vessel revascularization by means of rotablation and angioplasty. One patient was treated medically. No patient had a myocardial infarction from discharge up to 6 months' follow-up. The adverse events are shown in Table 2.

### Stent Group

The stent group consisted of 51 patients. The mean length of stay in the hospital was 3 days (range, 1-22 days). Five patients had a myocardial infarction after stenting, 3 as a result of an occlusion of a diagonal branch, 1 because of an occlusion of the stent (described below), and 1 because of a dissection. Return of angina pectoris resulted in (prolonged) hospitalization in 5 patients. Two patients were treated with additional medication, and 3 patients required repeat revascularization for in-stent restenosis. One patient was treated

**TABLE 2. Adverse events during the first 6 months**

| | MICAB (n = 51) | PTCA + stenting (n = 51) | *P* value |
|---|---|---|---|
| Death | 2 | 0 | .50 |
| Nonfatal myocardial infarction | 1 | 5 | .21 |
| CVA | 0 | 1 | 1.00 |
| Rethoracotomy | 1 | 0 | 1.00 |
| Dissection of LAD | 0 | 4 | .12 |
| Emergency CABG | 0 | 1 | 1.00 |
| Atrial fibrillation | 2 | 0 | .50 |
| Pericarditis | 1 | 0 | 1.00 |
| Pleural herniation | 1 | 0 | 1.00 |
| Wound-healing problem | 1 | 0 | 1.00 |
| Return of angina pectoris | 3 | 5 | .72 |
| Hospitalization for unstable angina pectoris | 1 | 2 | 1.00 |
| Restenosis | 2 | 4 | .68 |
| Repeat revascularization | 2 | 4 | .68 |

Values are number of patients per clinical event category. The number of patients with at least one event are presented, and no patient double counting for multiple events within a category was done. Between categories, patients are double counted in case of multiple events.

**TABLE 3. Patients' clinical characteristics at 6 months**

| | MICAB (n = 49) | PTCA + stent (n = 51) | *P* value |
|---|---|---|---|
| CCS classification | | | .25 |
| Class 0 | 92% | 80% | |
| Class 1 | 2% | 10% | |
| Class 2 | 6% | 8% | |
| Class 3 | 0% | 2% | |
| Class 4 | 0% | 0% | |
| Positive exercise test | 12% | 20% | .41 |
| Peak exercise test (W) | 148 ± 6.8 | 150 ± 5.9 | .83 |
| Peak heart rate exercise test (beats/min) | 131 ± 3 | 126 ± 3 | .22 |
| Triple therapy | | | .11 |
| No β/ca-ant/l.a.nit. | 31% | 18% | |
| One of β/ca-ant/l.a.nit. | 43% | 37% | |
| At least 2 of β/ca-ant/l.a.nit. | 26% | 45% | |
| Quality of revascularization | | | <.001 |
| No abnormalities or small irregularities | 87% | 22% | |
| Nonsignificant stenosis (20%-50%) | 9% | 49% | |
| Stenotic (≥50%) | 4% | 29% | |

β, β-Blocker; *ca-ant*, calcium antagonist; *l.a.nit.*, long-acting nitrate.

twice for in-stent restenosis after the first and fifth days after PTCA and stenting with a PTCA of the same lesion, eventually resulting in an occlusion and anteroseptal myocardial infarction. One patient was treated with re-PTCA and a cutting balloon after 2 months, and 1 underwent CABG after 4.5 months. No patients died. From discharge up to 6 months' follow-up, no patient had a myocardial infarction or needed to be hospitalized for another reason. The adverse events are shown in Table 2.

### Angiographic Outcome at 6 Months

Coronary angiography was performed in 96 of 102 patients because of refusal by 4 patients and the death of 2 patients (Table 3). QCA showed a stenosis (for definition, see "Patients and Methods" section) of the anastomosis in 2 patients after surgical intervention (2/46 [4%]) and restenosis in 14 patients after PTCA with primary stenting (14/49 [29%]). Therefore, angiographic outcome was significantly better after surgical intervention than after stenting ($P < .001$).

### Clinical Outcome at 6 Months

Secondary end points did not differ significantly. Log-rank testing on MACCEs ($P = .33$) and on MACCEs plus repeat target vessel revascularization ($P = .21$) proved these to be insignificant outcomes for both procedures (Figures 1 and 2). CCS status, exercise testing with a bicycle stress test, maximal workload capacity, and peak heart rate did not differ between the 2 groups (Table 3). Use of antianginal drugs did not significantly differ, although a slight trend of less need for antianginal drugs was found after MICAB (Table 3).

## Discussion

We report the first prospective randomized trial comparing MICAB with PTCA with primary stenting for isolated, proximal, high-grade (type B2 or C) stenosis of the LAD.

In this study MICAB had a significantly better angiographic outcome than PTCA with stenting at 6 months' follow-up. MICAB and PTCA with primary stenting did not significantly differ in regard to periprocedural complications, MACCEs, CCS status, use of antianginal medication, exercise test results, or repeat target vessel revascularization up to 6 months after revascularization. Two patients died in the MICAB group. An anastomotic problem could be ruled out in 1 patient at autopsy, and the other patient could not be evaluated, as explained in the "Results" section. Death did not occur in the PTCA with stenting group.

Mean hospitalization time after MICAB was 7 days, and that after PTCA with stenting was 3 days. This shorter convalescence period reflects the true minimally invasive character of PTCA with primary stenting.

After 6 months, angiographic outcome (either a nonstenotic LITA anastomosis in the MICAB group or a nonrestenotic LAD in the PTCA with stenting group) was significantly better in the MICAB group (96% vs 71%, $P < .001$). This 6-month patency rate of MICAB (96%) equals earlier reported off-pump patency rates and the benchmark patency of on-pump coronary bypass surgery.[1,6,8-11] Therefore, the known long-term ITA graft patency rate of almost 96% after 10 years in on-pump coronary bypass surgery can be expected for our MICAB population.[12] The restenosis rate after PTCA with stenting (71%) reflects the restenosis prob-

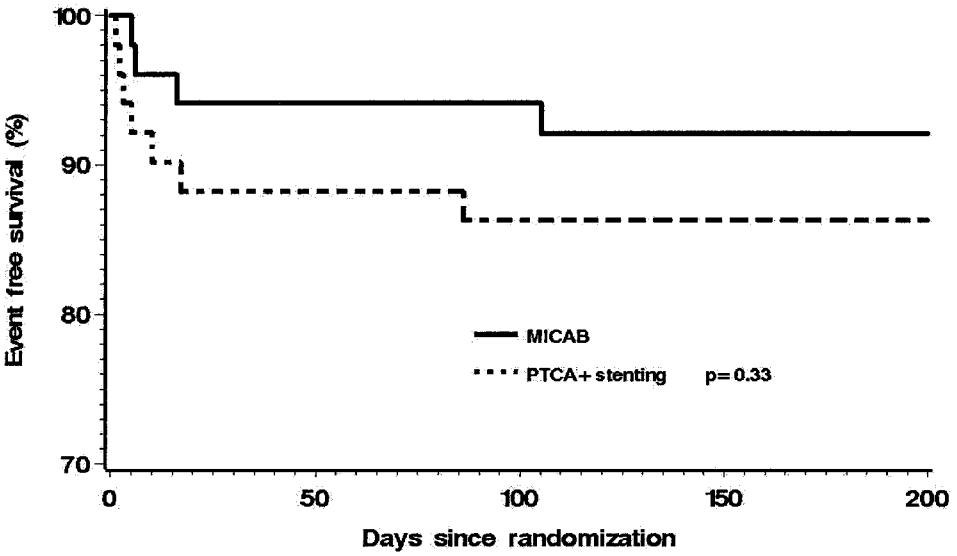


**Figure 1. Kaplan-Meier curves showing survival free from MACCEs after MICAB *(black line)* and PTCA with stenting *(dotted line).***

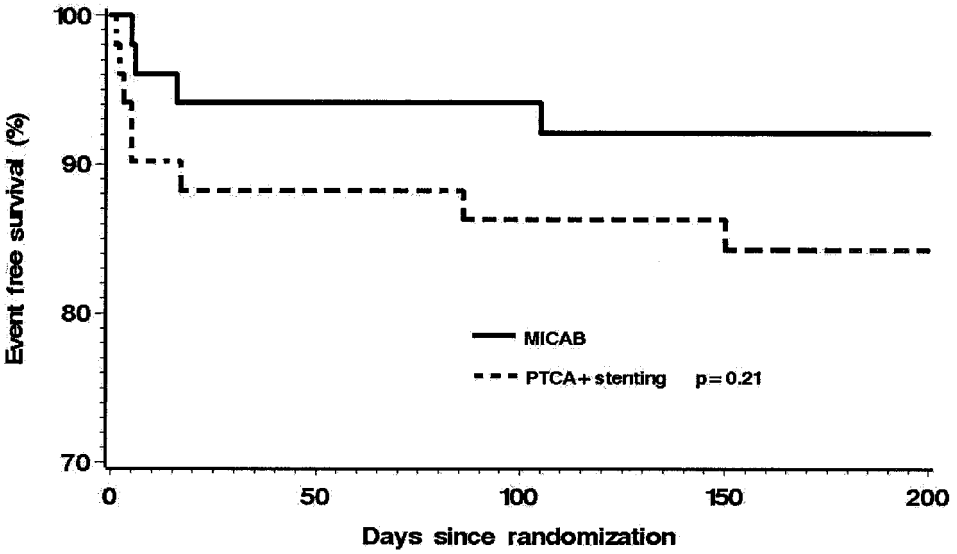


**Figure 2. Kaplan-Meier curves showing survival free from MACCEs and repeat target vessel revascularization after MICAB *(black line)* and PTCA with stenting *(dotted line).***

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lem and is a high relative risk for future repeat revascularizations and MACCEs.[13] Although repeat target vessel revascularization did not differ significantly at 6 months, a difference can be expected for these 2 reasons after a longer follow-up period. This was found in a recent prospective randomized trial comparing conventional CABG with the ITA with PTCA with primary stenting for proximal, isolated, de novo LAD stenosis (the SIMA trial).[14] That study reported a significant difference in clinical outcome between the 2 treatment groups in favor of the CABG group after a mean follow-up period of 2.4 years. This was primarily because of the higher incidence of repeat revascularization in the PTCA with stenting group. In that study the incidence of death and myocardial infarction was similar in the 2 treatment groups. Also, the functional class, need for antianginal drugs, and quality-of-life assessment showed no significant differences.

In the present study we did not use GP2b3a receptor blockers after PTCA with stenting. It is suggested that their use might improve outcome because of a reduced restenosis

rate.[15] In our opinion, however, currently available PTCA and stenting techniques and adjunctive therapies will not equal patency rates after CABG (whether conventionally or minimally invasive). Only when the mechanisms of restenosis are fully understood and restenosis can be prevented might equal results be obtained.

Our study was initiated to find the optimal, minimally invasive treatment for complex lesions in the proximal LAD. On the basis of our results with MICAB and the promising patency rate for PTCA with stenting, we started this study on the revascularization options of tomorrow. Data acquired by means of randomized controlled studies are lacking on today's options to revascularize a high-grade lesion of the proximal LAD. In addition, clinical parameters (eg, diabetes mellitus comorbidity), stent design, direct stenting, and the use of GP2b/3a receptor blockers have major implications for the result of this revascularization strategy.[1,15-17] The clinical implication for PTCA with stenting and MICAB therefore lies in the results of studies like these and studies with longer follow-up.

## Conclusions

After 6 months, surgical intervention has a significantly better angiographic outcome than stenting in patients with a high-grade stenosis of the proximal LAD. Clinical outcome did not significantly differ between treatments.

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