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The Medicine, Angioplasty or Surgery Study (MASS): A Prospective, Randomized Trial of Medical Therapy, Balloon Angioplasty or Bypass Surgery for Single Proximal Left Anterior Descending Artery Stenoses

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Objectives. **This study sought to evaluate, in a prospective and randomized trial, the relative efficacies of three possible therapeutic strategies for patients with a single severe proximal stenosis of the left anterior descending coronary artery and stable angina.**

Background. **Although percutaneous transluminal coronary angioplasty and coronary artery bypass surgery are often performed in patients with a single proximal stenosis of the left anterior descending coronary artery, it is unclear whether revascularization offers greater clinical benefit than medical therapy alone.**

Methods. **At a single center, 214 patients with stable angina, normal ventricular function and a proximal stenosis of the left anterior descending coronary artery >80% were randomly assigned to undergo mammary bypass surgery (n = 70), balloon angioplasty (n = 72) or medical therapy alone (n = 72). Angioplasty had to be considered technically feasible in every case. The predefined primary study end point was the combined incidence of cardiac death, myocardial infarction or refractory angina requiring revascularization.**

Results. **At an average follow-up period of 3 years, a primary end point had occurred in only 2 patients (3%) assigned to bypass surgery compared with 17 assigned to angioplasty (24%) and 12 assigned to medical therapy (17%) (p = 0.0002, angioplasty vs. bypass surgery; p = 0.006, bypass surgery vs. medical treatment; p = 0.28, angioplasty vs. medical treatment, all by log-rank test). There was no difference in mortality or infarction rates among the groups. However, no patient allocated to bypass surgery needed revascularization, compared with eight and seven patients assigned, respectively, to coronary angioplasty and medical treatment (p = 0.019). Both revascularization techniques resulted in greater symptomatic relief and a lower incidence of ischemia on the treadmill test; however, all three strategies eventually resulted in the abolition of limiting angina.**

Conclusions. **The more aggressive therapeutic approach with initial bypass surgery for patients with a single severe proximal stenosis of the left anterior descending coronary artery is associated with a lower incidence of medium-term adverse events than coronary angioplasty or medical treatment. However, all three strategies resulted in a similar incidence of death and infarction during an average follow-up period of 3 years. This information should be taken into consideration when physicians and patients make therapeutic choices in this setting.**

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Although prior studies (1,2) have demonstrated no difference in survival or myocardial infarction rates in patients with single-vessel disease who undergo revascularization procedures or receive medical therapy, these patients represent a heterogeneous group. This heterogeneity is particularly true for patients with stenosis of the left anterior descending coronary artery because the extent of myocardium at risk varies, depending in part on the amount of territory supplied by the vessel and in part on the location of the stenosis (3). Indeed, patients with proximal lesions before the first septal perforator have a significantly worse prognosis than those with distal disease in the same vessel (4).

Most of the information concerning the comparative usefulness of medical and surgical therapy in patients with stable angina is derived from the classic randomized studies performed in the 1970s. However, both medical therapy and surgical techniques have evolved significantly since then. One such example in the surgical field is the increasing use of the internal mammary artery grafts, now recognized for their association with improved long-term survival and freedom from cardiac events compared with that for saphenous vein grafts (5). Medical therapy has also evolved, with increased recognition of the benefits of antiplatelet, thrombolytic and beta-adrenergic blocking agents and angiotensin-converting enzyme inhibitors (6–8). Another factor is the frequent use of percutaneous transluminal coronary angioplasty. Coronary an-

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gioplasty was initially described after completion of enrollment in the large randomized trials of surgical and medical therapy in patients with stable angina. However, despite the widespread use of this procedure, its specific role vis-à-vis medical and surgical therapy remains to be established. Although several ongoing randomized trials comparing surgical revascularization and angioplasty are underway, none has a medical treatment arm (9–15).

Specifically, there are no relevant up-to-date data comparing medical, surgical and angioplasty therapies for patients with proximal left anterior descending coronary artery disease. The purpose of the present study was to evaluate whether coronary angioplasty or bypass surgery offers any advantage over medical therapy in patients with stable angina, normal left ventricular function and a single severe proximal stenosis of the left anterior descending coronary artery.

Methods

Study patients. To increase the homogeneity of the three treatment groups, only patients screened and treated at a single institution, the Heart Institute of the University of São Paulo, were included in the study. In addition, the surgeon and the interventional cardiologist who participated in the trial had considerable experience, defined as the performance of >10,000 procedures each. These two investigators were the sole operators of revascularization procedures in the present trial. Medical care and follow-up was provided by a senior staff cardiologist with >15 years of experience in treating coronary artery disease. Patients with unstable angina, prior infarction, significant valvular disease, cardiomyopathy, left ventricular dysfunction, a previous coronary intervention or prior open heart surgery were excluded. Patients from other states or those unable to make regular hospital visits were also excluded. Written informed consent was obtained from all patients. Both the consent form and the study protocol were approved by our institute's committee on ethics and human research.

From 1988 to 1991, we enrolled 214 patients with stable angina and single-vessel disease with at least 80% diameter stenosis in the left anterior descending coronary artery before the first diagonal branch. *Angiographic exclusion criteria* were total occlusion, lesion length >12 mm, involvement of the ostium, heavy calcification, severe tortuosity and stenosis of the left main coronary artery. The left anterior descending coronary artery lesion was above the first septal perforator in 89% of the patients on average, and the three treatment groups were similar with respect to lesion location. All cine films were reviewed by a cardiac surgeon, an interventional cardiologist and the attending physician. Either revascularization strategy had to be considered technically feasible by the consensus of the three investigators before randomization.

If the treatment failed, patients could be withdrawn from the protocol by their attending physician and assigned to a different treatment. If refractory angina occurred, patients assigned to medical therapy underwent angioplasty or bypass surgery. Patients initially allocated to angioplasty usually underwent surgical revascularization, and those who underwent initial surgical revascularization also underwent angioplasty. Repeat angioplasty in the event of restenosis was permitted as an integral part of the angioplasty strategy, and the procedure was repeated as many times as deemed necessary by the attending physician and interventional cardiologist. The maximal number of repeat procedures was four, and the average number of angioplasty procedures/patient was 1.6.

Twenty percent of the patients screened refused to participate in the trial; 5% were participants in other trials; 5% had unstable angina; 6% had previously undergone angioplasty; 2% had heart failure; 28% had lesions considered not suitable for coronary angioplasty; 19% had lesions <70% diameter stenosis, 8% had multivessel disease; and 10% had a left anterior descending coronary artery lesion involving the first diagonal branch and were excluded by mutual agreement of the investigators. In some patients, the presence of more than one factor led to their exclusion from the trial.

Medical therapy. Patients allocated to medical therapy alone received treatment according to a predefined approach that included aspirin, nitrates, beta-blockers and calcium channel blocking agents, unless contraindicated, to eliminate symptoms of angina.

Balloon angioplasty. Balloon angioplasty was performed according to standard protocols that included aspirin and, for most patients, nifedipine before the procedure. Intravenous heparin (10,000 U) and nitroglycerin were infused during the procedure. Coronary angiograms were repeated at 6 months or sooner if symptoms of angina recurred. Angioplasty was repeated if significant restenosis occurred. In the event of abrupt closure of the dilated artery, the interventional cardiologist and attending physician were allowed to decide whether to refer the patient for emergency bypass surgery.

Surgical revascularization. All patients assigned to surgical revascularization underwent bypass grafting using the left internal mammary artery. Extracorporeal circulation was used for all patients, and the perfusion rate was maintained at 2.0 to 2.4 liters/m^2 per min under mild hypothermia (34 to 35°C). The anastomoses were performed during a short period of cardiac arrest after aortic cross-clamping. Distal anastomoses were performed under optical magnification.

Follow-up. After discharge, all patients were seen and examined every 3 mo at the Heart Institute. Unless contraindicated, all patients received aspirin, nitrates and beta- and calcium channel blockers. Patients underwent a symptom-limited treadmill exercise test at baseline and after 2 years of randomization according to a modified Bruce protocol, unless contraindicated. Coronary angiography was repeated in all patients after 2 years. Patients assigned to coronary angioplasty underwent routine coronary angiography also at 6 months.

Study end points. The predefined primary study end point was the combined incidence of cardiac death, myocardial infarction or refractory angina requiring revascularization. Surgical revascularization, but not repeat coronary angioplasty, was considered an end point for patients assigned to coronary angioplasty. Secondary outcomes were angina functional class

at the last follow-up visit, employment status and positive exercise test results 2 years after enrollment and degree of atherosclerotic involvement of the coronary arteries at the 2-year angiographic study.

Symptoms of angina were graded according to severity, from 1 to 4, as previously defined (16). Refractory angina was considered only when patients had been treated with anti-ischemic therapies (usually triple-drug therapy) to their tolerance level. Myocardial infarction was defined by the development of significant new Q waves in at least two electrocardiographic leads or when symptoms were compatible with a myocardial infarction associated with elevation of the creatine kinase, MB fraction to greater than three times the upper limit of normal.

Ventricular function. Patients underwent contrast left ventriculography during the baseline and follow-up cardiac catheterizations in the right anterior oblique projection. The endocardial contours were traced during systole and diastole of a normal sinus beat, and the global left ventricular ejection fraction was obtained using the area-length method, as previously described (17).

Statistical analysis. Data are reported as mean value ± SD. Discrete variables in the groups were compared by the Fisher exact and chi-square tests, and continuous variables were compared using analysis of variance. The event-free probabilities in the groups were estimated by the Kaplan-Meier method and compared by the log-rank test. All analyses were performed according to intention to treat, and the reported statistics are two-tailed; $p < 0.05$ was considered significant.

Results

Patients. Two hundred fourteen patients met all entry criteria and were randomized to undergo bypass surgery (70 patients), balloon angioplasty (72 patients) and medical treatment alone (72 patients). The three groups did not differ with respect to baseline clinical, angiographic and laboratory characteristics, as shown in Table 1. The average follow-up period was 3.5 ± 1.5 years.

Primary end points. *Medical therapy.* In the medical therapy group, two patients sustained an uncomplicated myocardial infarction, four were referred for bypass surgery, and three were referred for angioplasty because of refractory angina. There were no deaths or strokes.

Bypass surgery. Of the 70 patients assigned to left internal mammary artery bypass surgery, one patient had a perioperative infarction, and one died on the way to the hospital after the onset of chest pain 43 mo after bypass surgery. No patient required angioplasty and there were no strokes.

Coronary angioplasty. Angioplasty was clinically successful in 96% of the 72 patients initially assigned to coronary angioplasty. It was not possible to dilate the stenosis in three patients, two of whom had a periprocedural myocardial infarction and were referred for emergent bypass surgery. During the follow-up period, 27 patients assigned to this group (37.5%) had repeat angiography because of refractory angina, and 21 underwent one or more additional angioplasty procedures. Eight patients had refractory angina requiring elective bypass surgery. No patient was referred to bypass surgery solely as a result of 6-month follow-up angiography. One patient assigned to angioplasty died suddenly at home 8 months after the procedure. There were no strokes.

Table 1. Baseline Characteristics of 214 Study Patients

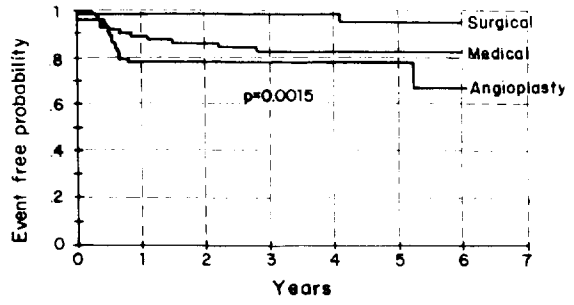
	Medical Therapy (n = 72)	PTCA (n = 72)	Mammary Bypass (n = 70)
Clinical			
Age (yr)	58 ± 7	54 ± 9	58 ± 11
Male gender (no.)	59	58	58
Hypertension (%)	38	34	30
Diabetes (%)	20	15	18
Current smoker (%)	36	36	37
Employed (%)	89	88	90
Laboratory values (mg/dl)			
Total cholesterol	240 ± 40	213 ± 49	230 ± 45
LDL cholesterol	162 ± 36	141 ± 42	155 ± 36
HDL cholesterol	41 ± 9	38 ± 9	37 ± 8
Triglycerides	199 ± 111	192 ± 126	220 ± 110
Positive Tl-201 stress scintigraphic results (%)	86	82	84
Angiographic findings			
Mean stenosis (%)	89	86	88
Ejection fraction (%)	74 ± 4	77 ± 6	74 ± 4

Unless otherwise indicated, data presented are mean value ± SD. HDL = high density lipoprotein; LDL = low density lipoprotein; PTCA = percutaneous transluminal coronary angioplasty; Tl = thallium.

The *event-free probability* at an average follow-up period of 3 years in the patients initially allocated to bypass surgery was 97%, significantly greater than that for those assigned to the other two groups and did not differ between those randomized to coronary angioplasty (76%) and those randomized to medical therapy (83%) ($p = 0.0002$ for coronary angioplasty vs. bypass surgery; $p = 0.006$ for bypass surgery vs. medical treatment, log-rank test) (Fig. 1).

Angina. There was a marked suppression of angina in patients randomized to both revascularization strategies: 68 patients assigned to bypass surgery (98%) and 58 randomized to coronary angioplasty (82%) were totally asymptomatic at the last follow-up visit an average of 3 years after enrollment. In contrast, only 23 patients randomized to medical treatment (32%) were asymptomatic at the 3-year follow-up visit ($p < 0.01$ for bypass surgery vs. coronary angioplasty; $p < 0.01$ for coronary angioplasty vs. medical treatment). No patient in any randomized group had limiting angina (functional class III or IV) at the last follow-up visit.

Treadmill test. One hundred sixty-five patients underwent exercise treadmill tests after 2 years of follow-up. Ninety-four percent of those randomized to bypass surgery, 79% of those to assigned coronary angioplasty and 34% of those assigned to medical therapy were ischemia free on this stress test ($p < 0.01$ for medical therapy vs. both revascularization strategies).



Angioplasty	72	56	45	32	14	9
Surgical	70	68	56	42	27	13
Medical	72	63	54	38	20	10

Figure 1. Event-free probability for the three treatment groups during the follow-up period. Note that the patients assigned to bypass surgery had a lower incidence of events during follow-up (Kaplan-Meier analysis; see Methods for definition of events). **Numbers** below the graph are number of patients reaching each time point in each group.

Employment status. There was no difference among the groups with respect to the proportion of patients regularly working 2 years after randomization. Fifty-six of the patients assigned to medical treatment (78%), 46 of those randomized to coronary angioplasty (64%) and 56 of those who initially underwent bypass surgery (80%) were employed (p = NS).

Angiography. All patients agreed to undergo repeat angiography after 2 years of randomization. Fifty-four of these patients (35%) had evidence of progression to >50% diameter stenosis in a vessel that did not have significant disease previously. This progression occurred in 16 of the 54 patients assigned to bypass surgery, 19 of the 52 allocated to angioplasty and 19 of the 53 assigned to medical therapy (p = NS). There was no relation between baseline or follow-up total or fractionated cholesterol levels and angiographic progression of disease. Baseline and follow-up total cholesterol levels were, respectively, 225 ± 42 and 231 ± 44 mg/dl for those with new lesions and 236 ± 51 and 224 ± 42 md/dl for those without new lesions (p = NS).

At 2-year follow-up angiography, 47 patients assigned to medical therapy (89%) had a lesion 70% to 99% diameter stenosis, and 6 had an occluded artery (11%). Thirty-three patients allocated to coronary angioplasty (63%) had a lesion <70% diameter stenosis; 15 (29%) had 70% to 99% diameter stenosis; and 4 (8%) had total occlusion of the left anterior descending coronary artery. Two patients assigned to bypass surgery (4%) had <70% diameter stenosis; 12 (22%) had 70% to 99% narrowing; and 40 (74%) had total occlusion of the left anterior descending coronary artery. Left internal mammary angiography disclosed no atherosclerosis and a patent anastomosis in all but one patient 2 years after bypass surgery.

Baseline and follow-up global left ventricular ejection fraction was 74 ± 4% and 71 ± 7% for those assigned to medical treatment, 77 ± 6% and 73 ± 7% for those assigned to coronary angioplasty and 73 ± 4% and 71 ± 5% for those undergoing bypass surgery (p = NS among the groups and for baseline vs. follow-up studies).

Discussion

Autopsy and nonrandomized studies (3,4,17–19) emphasize the prognostic importance of severe proximal lesions of the left anterior descending coronary artery. More aggressive therapy is also recommended for patients with severe proximal left anterior descending coronary artery disease because of the widespread assumption that prognosis is ultimately related to the amount of myocardium at risk (20,21).

Balloon angioplasty was introduced in the late 1970s as a less invasive form of limited coronary revascularization (22) and has since grown explosively. There were >300,000 angioplasty procedures performed in the United States in 1991, most of them single-vessel disease procedures, and, surprisingly, many were not performed in accordance with the established indications as outlined in some guidelines for the procedure (23). More recently, newer coronary angioplasty techniques have been compared with traditional balloon coronary angioplasty in patients with proximal left anterior descending coronary artery stenoses (24). Despite a slight increase in the procedural success rate with atherectomy devices, there was still a significant proportion of in-hospital complications, and the restenosis rate during follow-up remained high. There are also few data assessing the relative efficacies of coronary angioplasty and surgical revascularizations, and this issue has been the focus of ongoing trials comparing these treatments in different subsets of patients with coronary artery disease (10–12,14,15).

Nevertheless, despite the more guarded prognosis associated with left anterior descending coronary artery involvement versus that for other coronary arteries, the outlook for all patients with single-vessel disease and preserved ventricular function is generally good, and it is not clear whether revascularization strategies result in better medium- or long-term outcomes than medical therapy alone.

Study findings versus previous trials. We studied 214 carefully selected patients with stable angina randomized to the three available therapies for single proximal left anterior descending coronary artery stenosis. All three interventions resulted in significant symptomatic relief, although the proportion of patients totally asymptomatic in the medical arm (32%) was significantly less than those in the coronary angioplasty (82%) and surgical (98%) groups. These results are in agreement with data published recently from the Angioplasty Compared to Medicine (ACME) trial (13), indicating that patients with single-vessel disease assigned to coronary angioplasty have more complete angina relief than do those assigned to medical therapy. However, all three therapies in this study resulted in the elimination of limiting angina, and the symptomatic benefit in the revascularization groups may not be clinically important. Mammary bypass surgery was associated with a greater event-free probability at an average follow-up of 3 years than either coronary angioplasty or medical treatment. This benefit resulted from a very low surgical periprocedure complication rate, as well as the successful medium-term abolition of symptoms, which completely eliminated the need

for a repeat revascularization procedure. These results are comparable to other published series of patients with isolated left anterior descending coronary artery disease treated with bypass surgery (25). Death and infarction rates were also low in patients assigned to medical therapy and angioplasty. However, these treatments were associated with higher crossover rates to the other treatment arms because of the development of refractory angina during the follow-up period.

The relatively benign course in the nonsurgical patients with proximal left anterior descending coronary artery narrowing observed in the present study may be related in part to the normal ventricular function in our patients. Klein et al. (4) evaluated a group of patients with left anterior descending coronary artery disease and normal ventricular function and reported a survival rate of 97% over an average follow-up period of 17 months. However, the presence of proximal left anterior descending coronary artery stenosis was a better predictor of worse outcome than was altered anterior wall motion. In patients medically managed with normal left ventricular function, Califf et al. (3) reported a survival rate of 98% in those with isolated left anterior descending coronary artery disease located after, and 90% with disease located before, the first septal perforator at 5 years of follow-up.

The only other randomized comparison of coronary angioplasty and bypass surgery for the treatment of patients with isolated proximal left anterior descending coronary artery stenosis was recently reported by Goy et al. (12). In a similar group of 134 patients with stable angina, they observed that 86% of surgically revascularized patients and 43% of coronary angioplasty–treated patients were free of adverse events after a median follow-up period of 2.5 years. These results parallel the significantly higher event-free probability of the patients who underwent bypass surgery in the present study (97% for bypass surgery vs. 76% for coronary angioplasty, $p < 0.01$). The lower proportion of events occurring during follow-up in the present report probably reflects a stricter definition of events and end points. However, in neither study was there a difference in cardiac death or myocardial infarction rates between coronary angioplasty and surgical revascularization. Also, Goy et al. (12) did not randomize a comparable group of patients to medical therapy alone.

A comparison between balloon-expandable stent implantation and balloon angioplasty in patients with single-artery disease has been recently reported (26). During a 7-month follow-up period, there was an improvement in clinical and angiographic outcomes in patients receiving stents compared with those who underwent balloon angioplasty only, who were at a significantly higher risk of vascular complications and a longer hospital stay. All patients in the present study who were treated by angioplasty underwent standard balloon angioplasty. Thus, it is unclear whether the use of newer interventional techniques such as stent implantation would alter the results presented here.

We also observed significant progression of coronary atherosclerosis during the study. At 2-year follow-up angiography, 35% of the patients had developed >50% stenosis in vessels previously free of significant narrowing at the baseline examination. The atherosclerotic involvement of coronary arteries other than the left anterior descending coronary artery transforms the status of these patients from single-vessel to multivessel disease, which could significantly influence the clinical course and treatment strategies adopted.

Conclusions and clinical implications. The use of mammary bypass surgery for the treatment of patients with stable angina and isolated, severe proximal stenosis of the left anterior descending coronary artery with normal ventricular function was associated with a higher event-free survival rate due to a lower reintervention rate than coronary angioplasty or medical treatment alone during an average follow-up period of 3 years. However, there was significant progression of coronary atherosclerosis in nontreated vessels in all groups, and the three therapeutic strategies resulted in a similar success rate in terms of abolishing limiting angina and an equally low incidence of death or myocardial infarction during the 3-year follow-up period. Future cost-benefit analyses as well as longer follow-up studies are warranted. Ongoing efforts toward a meta-analysis of all available randomized data may result in greater insight into the effects of these interventions on hard end points, such as mortality and infarction rates.

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