The Effect of Internal Mammary Artery Grafts on Long-Term Clinical Outcomes After Coronary Bypass Surgery

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ABSTRACT

***Background*.** Internal mammary artery (IMA) grafts have better patency than vein grafts, but their effects on long-term clinical outcomes after coronary bypass surgery have been evaluated in only a few studies.

Methods and Results. We analyzed clinical outcomes over a median follow-up of 5.9 years among 3,087 patients who received coronary bypass surgery as participants in one of eight clinical trials comparing surgery with angioplasty. We used two statistical methods (covariate adjustment and propensity score matching) to adjust for the non-randomized selection of IMA grafts. Both methods showed lower mortality associated with IMA grafting, with hazard ratios (confidence intervals) of 0.77 (0.62 to 0.97) for covariate adjustment and 0.77 (0.57 to 1.05) for propensity score matching. The composite endpoint of death or myocardial infarction was reduced to a similar extent, with hazard ratios of 0.83 (0.69 to 1.00) for covariate adjustment to 0.78 (0.61 to 1.00) for propensity score matching. There was a non-significant trend towards less angina at one year, with odds ratios of 0.81 (0.61 to 1.09) in the covariate adjusted model and 0.81 (0.55 to 1.19) in the propensity score adjusted model.

***Conclusion*.** Use of an IMA graft during coronary bypass surgery seems to improve long-term clinical outcomes.

Key Words: Coronary disease, revascularization

The internal mammary artery (IMA) has better long-term patency than the saphenous vein when used as a conduit in coronary artery bypass graft surgery (CABG) (1-3). While it is widely believed that this higher patency rate leads to better long-term clinical outcomes, there are few data to support this assumption. Only one randomized trial has compared use of IMA grafts with saphenous vein grafts (4). In that trial, patients assigned to receive an IMA graft had fewer composite endpoints of cardiac death, myocardial infarction, repeat revascularization and cardiac hospitalization over 10 years (12 of 39 versus 21 of 41, $p<0.05$), but did not differ significantly in any other endpoint. The results of this trial are not definitive because of its small size and because the outcome differences were driven mostly by cardiac hospitalizations rather than death or myocardial infarction. Observational, non-randomized studies of between 743 and 5,931 patients who underwent CABG in the 1970s suggest that patients who received an IMA graft had improved long-term survival compared with patients who received only saphenous vein grafts (5-7). Patients selected to receive an IMA graft, however, differed in many clinical characteristics from patients selected to receive only vein grafts, and these differences may have introduced selection bias into the comparison of outcomes that can be difficult to control using statistical methods. Newer approaches to the analysis of observational data may help control for differences between patients selected for different treatments (8-11), although selection biases not captured by measured covariates may still exist (12). The purpose of this study was to apply both propensity score methods and covariate adjustment methods to compare the long-term outcomes of a more contemporary sample of patients who underwent CABG with or without an IMA graft.

Methods

Investigators from ten randomized trials of CABG versus percutaneous coronary intervention for multivessel coronary disease pooled individual patient data as part of a collaborative analysis of long-term treatment outcomes, as described previously (13). The present study is based on data from the eight trials that provided individual patient data on the use of IMA grafts among patients assigned to CABG (14-21). Use of IMA grafting in these trials was based on surgeon preference, and was not randomized.

We used multivariable logistic regression to compare baseline clinical characteristics of patients who received an IMA graft with those who did not. The results of this model were used to create a propensity score that estimated the probability of each patient receiving an IMA graft. For the propensity score matched analyses, we identified pairs of patients, one of whom received an IMA graft and one of whom did not, using an algorithm (22) that first paired the patients with the closest propensity scores, then paired the patients with the next closest propensity scores, etc., and stopped matching when propensity scores differed by more than 0.01. We required that each pair of patients be drawn from the same clinical trial, and be matched on the presence or absence of diabetes.

We assessed time-to-event for three major clinical outcomes: death; death or myocardial infarction; and death or myocardial infarction or repeat revascularization. These endpoints were defined by each trial using specific protocol definitions (14-21).

We used Cox proportional hazards models to analyze time-to-event outcomes, and logistic regression to analyze angina at one year. We performed two sets of analyses for each outcome. In the first set of analyses, we compared

outcomes of patients with and without an IMA graft among all patients, adjusting for patient baseline clinical characteristics (Table 1), and stratifying by trial. In the second set of analyses, we compared outcomes of patients with and without an IMA graft in the subset of patients who were matched on propensity score, adjusting for baseline clinical characteristics, and stratifying by trial. All statistical analyses were performed with R Version 2.8.1.

Results

Data on IMA use were available for 3,087 patients who received CABG in one of eight clinical trials. The 2,573 patients (83%) who received an IMA graft were significantly less likely to be female, to have heart failure or a prior myocardial infarction, and significantly more likely to have proximal disease of the left anterior descending coronary artery or triple-vessel disease (Table 1). The use of IMA grafts also varied significantly by trial, ranging from 39% in GABI (17) to 96% in ERACI-II (16). The multivariable propensity score showed that the strongest predictor of whether or not a patient received an IMA graft was the trial in which the patient was enrolled, followed by heart failure, presence of disease in the proximal left anterior descending artery, female gender, and the presence of three-vessel disease (Table 2). We were able to match on propensity score 437 of the 514 (85%) patients who did not receive an IMA graft with 437 patients from the same trial who did receive an IMA graft. As expected, the matched groups had very similar baseline characteristics (Table 1).

Among all patients receiving CABG, the unadjusted Kaplan-Meier mortality rate at five years was 2.6% lower among patients who received an IMA graft than patients who received vein grafts only, and at ten years the mortality rate was 1.9%

lower in the IMA group (Table 3). In a Cox model that was stratified by study and adjusted for all of the baseline characteristics in Table 1, use of an IMA graft was associated with a significantly lower risk of death, with a hazard ratio of 0.77 (confidence interval 0.62 to 0.97, p=0.02). Use of an IMA graft was also associated with a significantly reduced chance of the composite endpoint of death or myocardial infarction and the composite endpoint of death or myocardial infarction or repeat revascularization (Tables 3 and 4). Angina at one year was also less frequent among patients who received an IMA graft, but not significantly so (Tables 3 and 4).

Among 437 pairs of patients matched on propensity score, study and diabetes, five-year mortality was 2.3% lower among patients who received an IMA graft than among patients who did not, and at ten years mortality was 2.5% lower in the IMA group (Figure 1, Table 3). In a Cox model stratified by study, use of an IMA graft was associated with a lower risk of death, with a hazard ratio of 0.78 (confidence limits 0.57 to 1.05, p=0.10). The hazard ratio was essentially unchanged after additional adjustment for baseline characteristics (0.77, confidence limits 0.57 to 1.05, p=0.10). There was a significantly lower incidence of the composite endpoint of death or MI (Figure 2, Table 3) and of the composite endpoint of death, MI, or repeat revascularization (Figure 3, Table 3). Angina at one year was less frequent among patients who received an IMA graft, but not significantly so (Tables 3 and 4).

Discussion

Our analysis confirms that patients who receive IMA grafts differ significantly from patients who receive only vein grafts in a number of prognostically important clinical characteristics (Table 1), including sex, a history of MI and of heart failure, and extent of coronary disease (Table 2). After adjusting for these and other differences using several different statistical methods, we found that use of an IMA

graft was associated with 23% lower risk of death over a 5.9 year median follow-up (Table 4). These results are generally consistent with the 38% risk reduction over 10 years reported by Loop and associates (5), the 27% risk reduction over 15 years reported by Cameron and coworkers (6), and the 32% risk reduction over 20 years reported by Cameron and associates (7). The long-term risk reductions associated with use of IMA grafts are not as striking as the 56% to 74% reductions in procedural mortality reported by large clinical databases (23-26), but comparisons of 30-day mortality after CABG may be more susceptible to selection bias.

In addition to an association with lower mortality, IMA use in our study was also associated with lower rates of myocardial infarction, repeat revascularization, and angina (Tables 3 and 4). The consistency of the effect of IMA use on these additional endpoints is reassuring. Our results, in conjunction with earlier studies (5, 6) suggest that the better long-term patency of the IMA graft seems to translate into improved long-term clinical outcomes.

IMA grafting has not been tested in a large, long-term clinical trial, so non-randomized observational comparisons are the only source of information on the comparative effectiveness of IMA grafts and vein grafts. Patients selected for alternative treatments differ in a number of ways, however, so multivariable statistical methods have been used in an attempt to adjust for clinically important differences between patient groups. A variety of methods has been used (27), including direct adjustment for confounding factors in a multivariable model, propensity score adjustment and matching (8, 9), and instrumental variables methods (28, 29), among others. Typically, investigators choose just one of these methods to analyze their data, but recent studies have shown that the results of alternative models applied to the same dataset may well differ (30, 31). We applied

several approaches to the analysis of these data to evaluate whether the results would be affected by the choice of a statistical model. The magnitude of the effect of IMA on several outcome measures was quite similar whether we used direct adjustment for baseline covariates or propensity score matching, although the confidence limits were wider when sample size was reduced by matching. These alternative approaches may have yielded similar results in the present study because some adverse prognostic factors had a higher prevalence in the IMA group (three-vessel disease, proximal left anterior descending disease), while other adverse prognostic factors had a lower prevalence in the IMA group (abnormal left ventricular function, prior myocardial infarction). Consequently, prognosis at study entry may have been relatively similar in the IMA and vein graft groups due to offsetting imbalances in different baseline characteristics. Furthermore, all patients in this analysis had been selected to participate in a clinical trial, and may have had a narrower range of clinical characteristics than unselected patients undergoing CABG. The similarity in the results of alternative statistical approaches in our study should not be interpreted as showing these methods would yield equivalent results in other observational treatment comparisons.

This study has a number of limitations. While the data were drawn from clinical trials of CABG and coronary angioplasty, the use of IMA grafting was not randomized and varied considerably among the participating trials, and according to patient characteristics. We had only relatively simple clinical data available on all patients, so were unable to adjust for characteristics such as extent of atherosclerosis, and residual selection bias due to unmeasured confounders may be present (12). Finally, all patients underwent CABG between 1988 and 2000, and

may not completely reflect the results of contemporary CABG, although all were treated in centers with excellent cardiac surgical programs.

In conclusion, these data provide additional evidence that use of an IMA graft appears to improve long-term outcomes after CABG, and suggest that IMA use may be a reasonable process measure of the quality of care for CABG (32, 33).

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Table. 1. Baseline Characteristics by Use of Internal Mammary Artery

	All Patients			Matched Patients		
	No IMA	IMA	p	No IMA	IMA	p
	(N=514)	(N=2573)		(N=437)	(n=437)	
Age (mean)	61.0	60.3	0.15	60.7	60.6	0.74
Female	30%	22%	0.0002	28%	28%	0.84
Diabetes	17%	16%	0.82	13%	13%	1.00
Hypertension	45%	46%	0.62	44%	47%	0.35
Hyperlipidemia	52%	53%	0.52	51%	52%	0.61
Current Smoker	22%	25%	0.18	23%	19%	0.11
Proximal LAD	35%	52%	<0.0001	35%	34%	0.64
3-Vessel Disease	29%	39%	<0.0001	29%	27%	0.49
Unstable Angina	49%	46%	0.14	53%	52%	0.90
Previous MI	50%	45%	0.04	49%	48%	0.70
Heart Failure	7%	3%	0.0005	5%	4%	0.22
Abnormal LV Function	18%	17%	0.62	19%	19%	0.80
Peripheral Vascular Disease	13%	11%	0.13	13%	13%	0.89
Study						
ARTS	40	539		40	40	
BARI	163	729		152	152	
ERACI-II	9	198		9	9	
GABI	96	62		54	54	
MASS II	10	188		10	10	
RITA	126	364		116	116	
SoS	36	451		35	35	
Toulouse	34	42		21	21	

IMA = Internal mammary artery
LAD = Left anterior descending coronary artery
LV = Left ventricular
ARTS = Arterial Revascularization Therapies Study
BARI = Bypass Angioplasty Revascularization Investigation
ERACI-II = Argentine Randomized Study: Coronary Angioplasty with Stenting Versus Coronary Bypass Surgery in Multivessel Disease
GABI = German Angioplasty Bypass Surgery Investigation
MASS-II = Second Medicine, Angioplasty or Surgery Study
RITA = Randomized Intervention Treatment of Angina
SoS = Stent or Surgery

Table 2. Propensity Score for Receiving an Internal Mammary Artery Graft

	Coefficient	P-Value
Age (mean)	-0.013	0.045
Female	-0.485	0.0001
Diabetes	-0.072	0.63
Hypertension	-0.092	0.42
Hyperlipidemia	0.014	0.92
Current Smoker	-0.049	0.72
Proximal LAD	0.697	<0.0001
3-Vessel Disease	0.298	0.014
Unstable Angina	-0.024	0.87
Previous MI	-0.172	0.12
Heart Failure	-0.973	<0.0001
Abnormal LV Function	-0.006	0.97
Peripheral Vascular Disease	0.013	0.95
Study		
ARTS	Reference	
BARI	-0.883	<0.0001
ERACI-II	0.458	0.24
GABI	-3.055	<0.0001
MASS-II	-0.082	0.82
RITA	-1.661	<0.0001
SoS	0.056	0.82
Toulouse	-2.260	<0.0001
Intercept	3.266	<0.0001

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Table 3. Incidence of Clinical Outcomes in Follow-Up by Use of the Internal Mammary Artery, Based on Pooled, Unadjusted Data

Outcome	All Patients		Matched Patients	
	No IMA	IMA	No IMA	IMA
	(N=514)	(N=2573)	(N=437)	(n=437)
Death (%)				
5 years*	10.4	7.8	10.4	8.1
10 years*	22.5	20.6	21.7	19.2
Death or MI (%)				
5 years*	19.2	15.4	19.1	13.8
10 years*	33.3	30.4	32.2	27.6
Death, MI or Repeat Revascularization (%) H				
5 years*	20.1	14.3	19.8	16.9
10 years*	40.8	37.4	40.2	36.6
Angina at 1 year (%)	17.8	12.8	17.8	15.4

* Kaplan-Meier estimates

H Data omits the Toulouse Study

IMA = Internal mammary artery

MI = Myocardial infarction

Table 4. Comparative Outcomes: Hazard Ratio for IMA vs. No IMA in Cox Models Stratified by Study and Adjusted for Baseline Clinical Characteristics

	All Patients (N=3087)		Matched Patients (N=874)	
	Hazard Ratio (CI)	P	Hazard Ratio (CI)	P
Death	0.77 (0.62-0.97)	0.02	0.77 (0.57-1.05)	0.10
Death/MI	0.83 (0.69-1.00)	0.05	0.78 (0.61-1.00)	0.05
Death/MI/Repeat Procedure	0.82 (0.69-0.98)	0.03	0.85 (0.67-1.08)	0.18
Angina* (One Year)	0.81 (0.61-1.09)	0.16	0.81 (0.55-1.19)	0.28

* Logistic regression model used to assess angina at one year. The data shown are odds ratios (95% confidence interval).

CI = Confidence interval

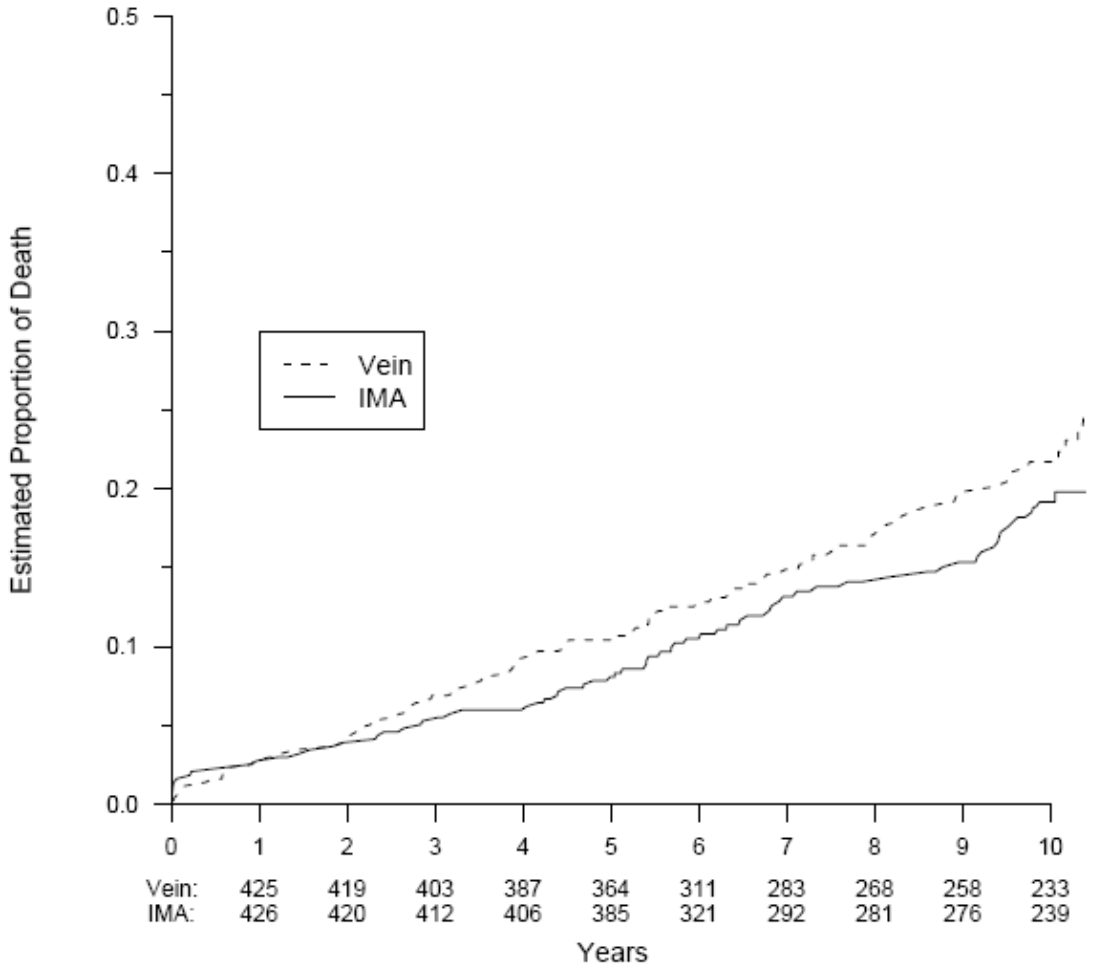
MI = Myocardial infarction

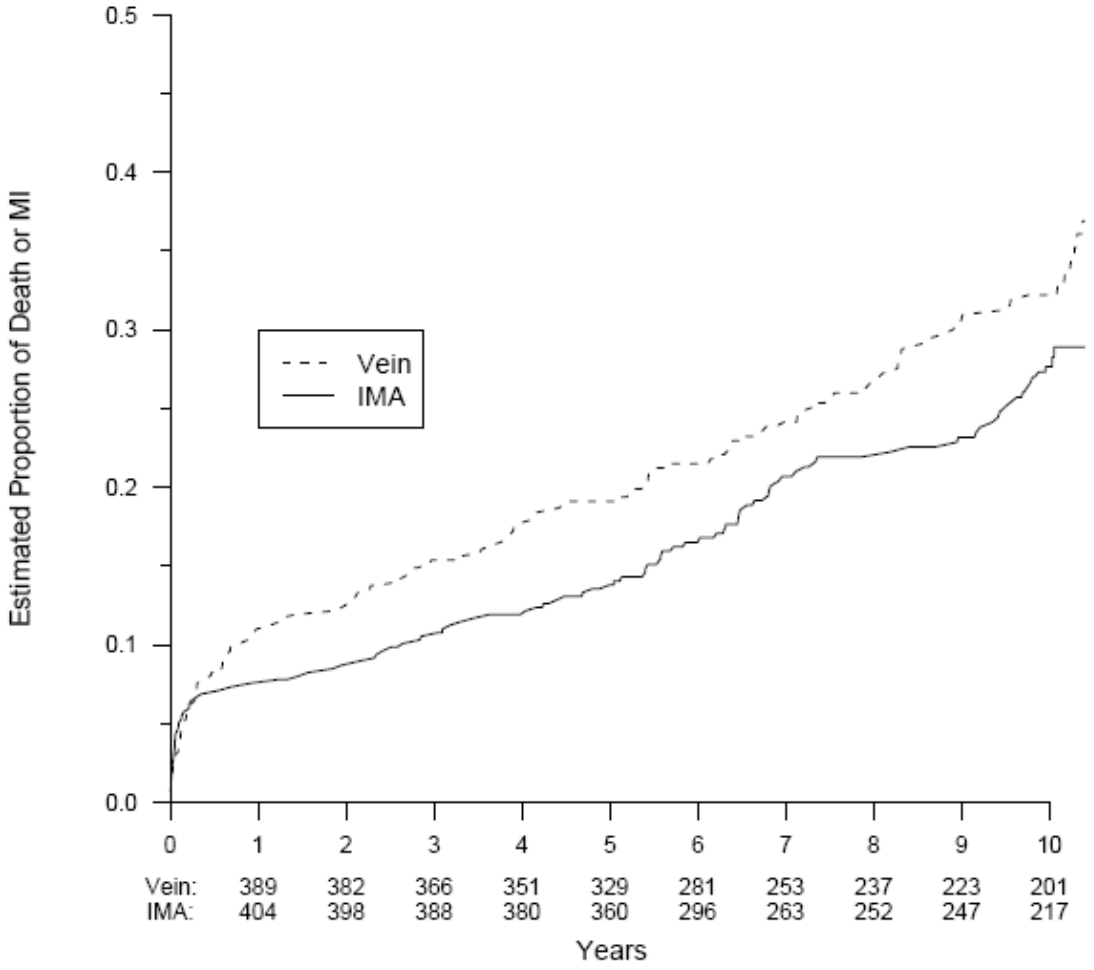
Figure Legends

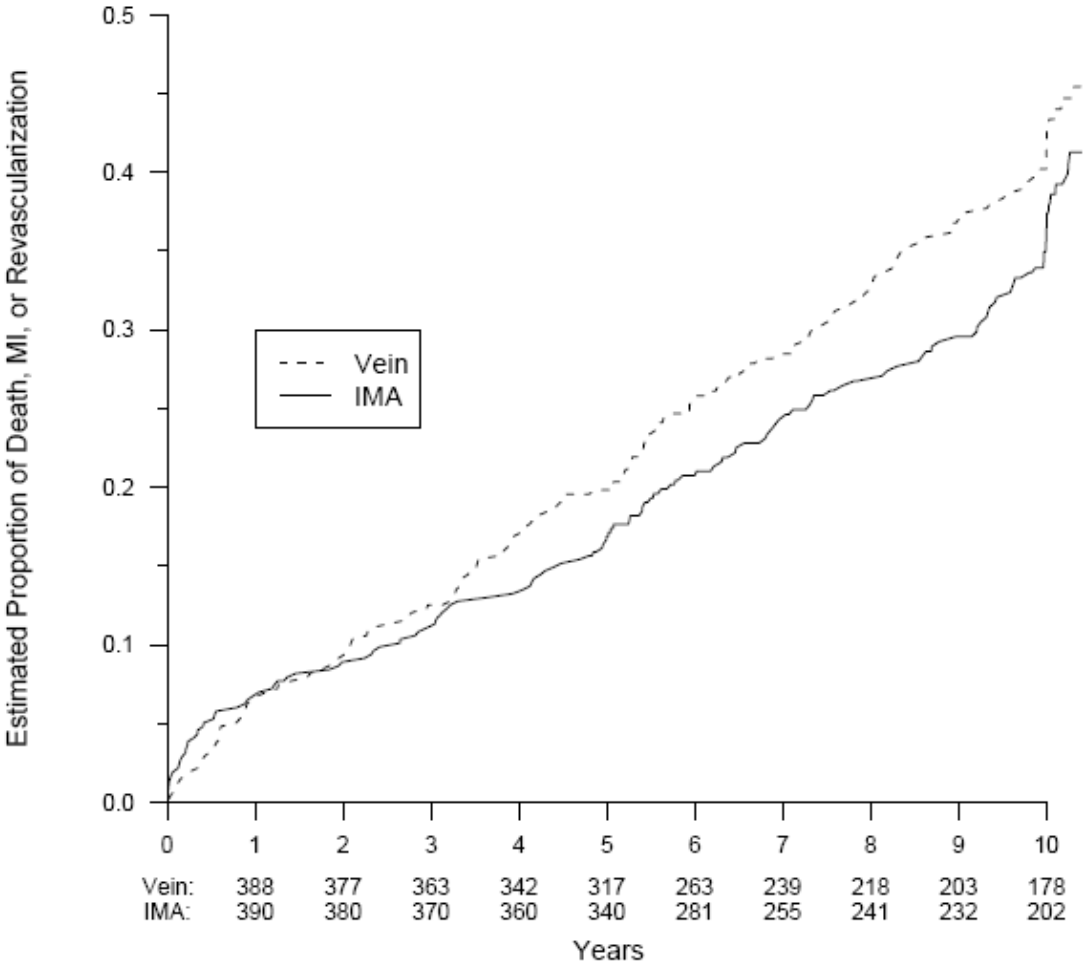
Figure 1. Cumulative rate of mortality (vertical axis) over ten years of follow-up (horizontal axis) in patients matched on propensity score. The outcome of patients who received an internal mammary artery (IMA) graft is indicated by the solid line and the survival of patients who received only vein grafts is indicated in the dashed line. The number of patients followed alive at each annual interval in each group is indicated below the horizontal axis.

Figure 2. Cumulative rate of death or myocardial infarction over ten years of follow-up. Format as in Figure 1.

Figure 3. Cumulative rate of death, myocardial infarction or repeat revascularization over ten years of follow-up. Long-term data on repeat procedures were not available from the Toulouse study. Format as in Figure 1.


Estimated Proportion of Death
0.5
0.4
0.3
0.2
0.1
0.0
Vein
IMA
0 1 2 3 4 5 6 7 8 9 10
Vein: 425 419 403 387 364 311 283 268 258 233
IMA: 426 420 412 406 385 321 292 281 276 239
Years


Estimated Proportion of Death or MI
0.5
0.4
0.3
0.2
0.1
0.0
Vein
IMA
0 1 2 3 4 5 6 7 8 9 10
Vein: 389 382 366 351 329 281 253 237 223 201
IMA: 404 398 388 380 360 296 263 252 247 217
Years


Estimated Proportion of Death, MI, or Revascularization
0.5
0.4
0.3
0.2
0.1
0.0
Vein
IMA
0 1 2 3 4 5 6 7 8 9 10
Vein: 388 377 363 342 317 263 239 218 203 178
IMA: 390 380 370 360 340 281 255 241 232 202
Years