Coronary Artery Surgery Study (CASS): Comparability of 10 Year Survival in Randomized and Randomizable Patients

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The Coronary Artery Surgery Study (CASS) includes 780 patients with mild or moderate stable angina pectoris or asymptomatic survivors of a myocardial infarction who were randomized to either medical or surgical therapy and 1,319 patients who were eligible for randomization but were not randomized (randomizable patients). There were no substantial aggregate differences observed in any of the survival comparisons after 10 years of follow-up study between the randomized and randomizable patients assigned to the medical (79% versus 80%) or surgical (82% versus 81%) groups or in patient subgroups stratified according to coronary artery disease extent and left ventricular ejection fraction.

Cox regression analyses were done with independent variables known to be predictors of survival, including surgical versus medical therapy and randomized versus randomizable group, to test the null hypothesis of a mortality difference between medical versus surgical assignment according to group assignment (randomized versus randomizable). In no case did the initial group category enter as a significant predictor of survival. The results in the randomizable group reinforce those in the randomized group with respect to the medical versus surgical comparison.

Two subgroups are identified with a significant surgical advantage: 1) patients with proximal left anterior descending coronary artery stenosis ≥70% and an ejection fraction <0.50, and 2) patients with three vessel coronary artery disease and an ejection fraction <0.50. In both groups, coronary bypass surgery had a statistically significant beneficial effect on survival ($p < 0.05$).

After a decade of follow-up, the CASS randomizable patients confirm conclusions reached on the basis of the CASS randomized trial.

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The Coronary Artery Surgery Study (CASS) recently reported (1) the 10 year survival data from 780 patients with mild or moderate stable angina pectoris or asymptomatic survivors of a myocardial infarction who were assigned to medical or surgical management on a formal randomized basis. The data show a similar 10 year survival rate for the medically versus surgically assigned patients (79% versus 82%; p = NS). When the patients were analyzed by subgroups, the 10 year survival rate was significantly greater in surgically assigned patients who had an ejection fraction <0.50 than in patients assigned to a strategy of initial medical management (79% versus 61%; $p = 0.01$). In patients with three vessel coronary artery disease and an ejection fraction <0.50, the 10 year survival rate was 75% versus 58% ($p = 0.08$) in the surgical versus the medically assigned patients. The 10 year survival rate for patients with less extensive coronary artery disease and for those with three vessel coronary disease and an ejection fraction ≥0.50 was similar in both groups (1).

The late results of the European Coronary Surgery Study

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(2) reveal a significant improvement in the survival rate in patients with three vessel disease and normal left ventricular function with surgical treatment, and the Veterans Administration randomized trial (3) reports findings similar to the CASS results. Differences in the results among the three randomized trials have been explained in part by differing baseline characteristics (4). The CASS randomized patients have been described (5) as a selected group at low risk who might have been expected to do well from the outset. In any randomized study, questions arise about the extent to which patients are representative of the population from which they are drawn and how that population is representative of the general patient population (4–6). The CASS trial is the only one of the three randomized medical-surgical trials in patients with coronary artery disease that was designed in a manner to allow this problem to be addressed, in part, by carefully collecting detailed clinical and angiographic descriptors of participants and by encompassing a registry of eligible patients from which the randomized cohort was drawn (7).

From August 1975 to May 1979, 780 patients were randomized to a strategy of medical management unless later symptoms required coronary revascularization or coronary bypass grafting. There were 1,319 patients eligible for randomization who were not randomized because the patients or their physicians declined participation in the randomized trial. The latter are referred to as the randomizable group; detailed entry characteristics and 5 year survival rates in this group have been previously reported (8). The aim of this report is to 1) compare the 10 year survival rate in medical randomized with medical randomizable patients and surgical randomized with surgical randomizable patients, and 2) examine whether inclusion in the randomized or randomizable cohort was a factor in determining the 10 year survival rate.

Methods

Study group. Coronary angiography was performed in 16,626 patients at 11 institutions participating in the randomized trial from August 1, 1975 to May 31, 1979. Of the 16,626 patients, 2,099 met randomization criteria; 780 were randomized and 1,319 constitute the randomizable group. The protocol was approved by the institutional review board at each participating institution, and all patients signed an informed consent form. Of the 780 randomized patients, 390 were assigned to the medical group and 390 to the surgical group. Of the 1,319 randomizable patients, 745 were in the medical group and 570 were in the surgical group. Baseline characteristics of the randomized and randomizable patients revealed a greater proportion of cigarette usage, hypertension and diabetes in the randomized group and a greater percent of patients with single vessel coronary disease and proximal left coronary artery disease in the randomizable group (Table 1).

Table 1. Entry Characteristics of Randomized and Randomizable Patients

	Randomized	Randomizable	p Value
No. of patients	780	1,315*	
Mean age (yr)	51	51	0.1
Male	90	91	0.1
Asymptomatic	22	21	0.1
Cigarette smoker	40	33	0.002
Previous MI	60	57	0.1
Hypertension	31	27	0.07
Diabetes mellitus	9	6	0.05
Peripheral artery disease	8	8	0.1
Normal electrocardiogram	29	29	0.1
1 VD >70% stenosis	27	32	0.06
2 VD >70% stenosis	40	35	
3 VD >70% stenosis	33	33	
LMCA stenosis 50%–69%	2	5	0.0001
Proximal LAD stenosis ≥70%	32	36	0.06
EF <0.50†	21	19	0.1

*Four randomizable patients excluded (see text); †measured in 1,723 patients. All data are percentages except as noted. LAD = left anterior descending coronary artery; LMCA = left main coronary artery; MI = myocardial infarction; VD = vessel disease.

Randomized and randomizable patients. Patients in the randomized trial were assigned to medical or surgical therapy on the basis of formal randomization. A randomizable patient was considered to be in the surgical group if he or she had surgery within 90 days of cardiac catheterization or within the period (for that institution) in which 95% of patients undergoing surgery within 1 year of cardiac catheterization had surgery, whichever was greater. The actual date of surgery determined the starting point for survival analyses (9). Randomizable patients who did not have surgery within this time interval constitute the medical group. The starting time for the medical patients was assigned from the average time to surgery as defined earlier. Of the 1,319 randomizable patients, 4 were not classified into either the medical or the surgical group; they died before the average time to surgery at their institutions, did not have surgery and are not considered in this report.

Angiographic and surgical descriptors. The number of diseased vessels was classified according to the number of luminal narrowings ≥70% in specific vascular territories as previously described (7), with the exception of the left main coronary artery where a 50% luminal narrowing was considered important. Of the 390 patients randomized to surgery, 96.3% had vein grafts and 16% had internal mammary artery grafts, reflecting the time period patients were enrolled into the CASS. Of the 570 randomizable patients assigned to surgery, 98.3% had vein grafts and 10% had internal mammary artery grafts. The average number of grafts inserted was 2.3 and 2.4 in the randomized and randomizable pa-

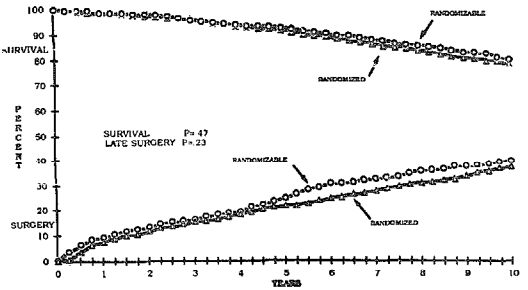

Figure 1. Medically assigned patients (n = 1,135). In the aggregate, the 10 year survival rate in randomized and randomizable patients was similar (p = 0.47). The percentage of patients who underwent late coronary bypass grafting was also similar (p = 0.23).

tients, respectively; the 30 day operative mortality rate was 1.4% and 1.2%, respectively.

Data acquisition. At entry, historical, clinical, laboratory and angiographic data were obtained for the randomized and randomizable patients in an identical manner. The only exception was that maximal symptom-limited exercise testing and determination of hematocrit, blood creatine, glucose, cholesterol and triglycerides was expected in the randomized patients but optional in the randomizable patients. During the follow-up period, randomized patients were examined at 6 month intervals. The status of randomizable and other registry patients was evaluated at 12 month intervals. A rest electrocardiogram (ECG) was obtained at 6 month intervals for 2 years and annually thereafter in randomized patients, whereas the ECG was obtained annually in randomizable patients.

Follow-up and data analysis. As of September 2, 1988, the mean duration of follow-up study was 10.6 years. Vital status is known for 778 randomized patients; 2 were lost to follow-up study after 4.5 and 10.5 years, respectively. Of the 1,319 randomizable patients, vital status is known for 1,313; 6 were lost to follow-up study after an average of 6.3 years (range 3 to 9).

Survival curves and time to surgery curves are given using the life table method. All follow-up data are used to compute the log rank statistic and two-sided p values (10). To further examine whether the experience of the randomizable group is different from that of the randomized group with respect to medical versus surgical comparison, Cox regression analyses were done with independent variables that have been shown to be predictors of survival in other studies (11,12); in addition, surgical versus medical therapy and classification of the patient as randomized or randomizable were included. After all variables were allowed to enter in a stepwise manner, the group variable (randomized or randomizable) was forced into the equation. This analysis includes all randomized and randomizable patients. Additional analyses on patient subgroups included analyses stratified by number of diseased vessels, ejection fraction and presence or absence of proximal left coronary artery disease.

The variables considered in the Cox analyses were: therapy (medical versus surgical), maximal stenoses of coronary artery segments, proximal left coronary stenoses, smoking, hypertension, diabetes mellitus, group selection (randomized versus randomizable), Canadian Cardiovascular Society angina classification (13), left main coronary artery disease, left ventricular contraction score, gender, age and prior history of myocardial infarction.

All p values should be interpreted cautiously because of the observational nature of the data and the multiple tests carried out.

Results

Follow-up results. There were no substantial or statistically significant differences observed in any of the survival comparisons between the randomized and randomizable patients in either the medical or the surgical group (Fig. 1 to 3, Tables 2 and 3). The 10 year incidence of coronary bypass surgery was similar in the randomized and randomizable patients who initially started in the medical group, with the exception of asymptomatic postmyocardial infarction survivors, where a greater percent of patients in the randomized cohort received surgery (40% versus 28%; p = 0.02). The rates of coronary angioplasty during the 10 year follow-up were 2.3% and 1.4% in the medical randomized and randomizable groups, respectively, and 2.6% and 1.3% in the surgical group, respectively.

For patients with three vessel coronary artery disease and stenoses ≥70% in the proximal left coronary artery, the 10 year survival rate was similar in both the randomized and

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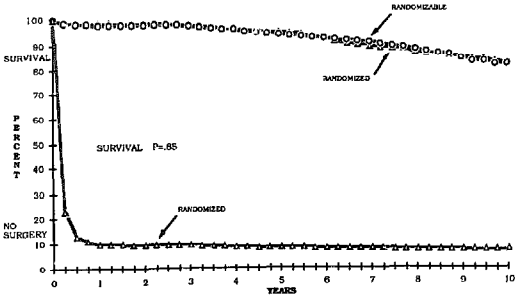
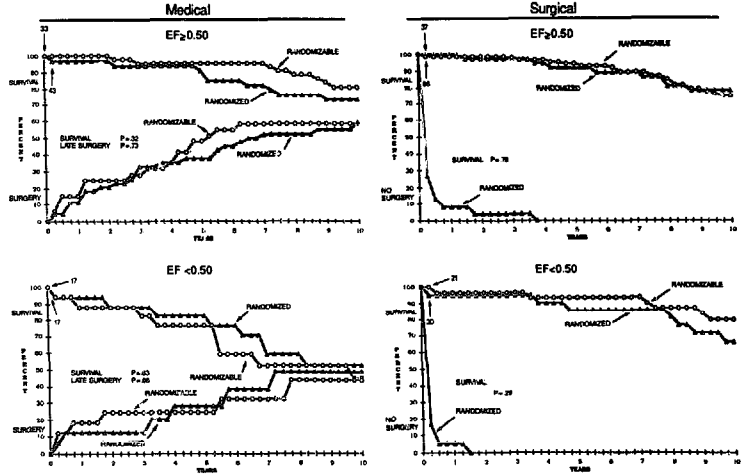


Figure 2. Surgically assigned patients (n = 960). In the aggregate, the 10 year survival rates in randomized and randomizable patients were virtually identical (p = 0.85). The percentage of patients assigned to surgery who did not undergo a coronary bypass operation was small, with >90% of patients operated on within 6 months of randomization.

Figure 3. The 10 year survival rate in patients with three vessel disease and proximal left coronary artery disease (stenoses ≥50% but <70% in the left main coronary artery or ≥70% in the proximal left anterior descending coronary artery). Medically assigned patients are represented in the **left panels** and surgically assigned patients in the **right panels**. At baseline, patients with an ejection fraction (EF) ≥0.50 are represented in the **upper panels** and those with an ejection fraction <0.50 in the **lower panels**. The number of patients at entry is indicated above the survival curve for the randomized patients and below the survival curve for the randomizable patients.



randomizable patients and in the medical and surgical groups stratified by ejection fraction (Fig. 3). Among patients assigned to the medical strategy, the percent of patients who underwent late coronary bypass grafting was similar in the randomized and randomizable groups. The results were similar when patients with left main coronary artery disease ≥50% to 69% were excluded.

Cox regression analysis. Cox regression analyses were applied to all of the randomized and randomizable patients.

Table 2. Ten Year Actuarial Survival in the Medical Group*

Group	Randomized			Randomizable		
	No.	Survival (%)	CABG (%)	No.	Survival (%)	CABG (%)
CCS I–II, EF >0.50	254	86 ± 5	42	482	85 ± 3	38
CCS I–II, EF <0.50	54	59 ± 14	28	124	65 ± 9	46
Asymptomatic post-MI	82	69 ± 10	40†	139	76 ± 8	28
EF <0.50	82	61 ± 11	34	103	60 ± 10	36
1 VD, EF <0.50	11	56 ± 30	11	26	54 ± 20	16
2 VD, EF <0.50	35	65 ± 17	28	43	71 ± 14	39
3 VD, EF <0.50	36	58 ± 16	49	34	52 ± 17	46
EF ≥ 0.50	284	84 ± 4	40	439	85 ± 4	38
1 VD, EF ≥0.50	95	85 ± 8	23	201	87 ± 5	27
2 VD, EF ≥0.50	99	85 ± 7	41	150	84 ± 7	47
3 VD, EF ≥0.50	90	84 ± 8	56	88	81 ± 9	48
1 VD, proximal LAD stenosis ≥ 70%	31	70 ± 17	29	53	89 ± 9	28
2 VD, proximal LAD stenosis ≥ 70%	36	78 ± 14	43	76	72 ± 11	54
3 VD, proximal stenosis LAD ≥ 70%	51	64 ± 14	54	75	64 ± 12	53
Total group	390	79 ± 4	40	745	80 ± 3	37

*$p > 0.10$ for all survival comparisons between randomized and randomizable patients; †$p > 0.10$ for all coronary bypass graft surgery comparisons between randomized and randomizable patients except for asymptomatic patients after myocardial infarction (post-MI) ($p = 0.02$); survival ± 95% confidence limits (CL). Because of multiple comparisons, a p value < 0.01 should be considered statistically significant. CABG = coronary artery bypass grafting by 10 years; CCS = Canadian Cardiovascular Society class; other abbreviations as in Table 1.

In no case did the initial group category (that is, being in the randomized or randomizable cohort) enter as a significant predictor of survival, even after adjustment for prognostic covariates. Thus, the argument that patient selection for the randomized trial resulted in nonrepresentative findings is not supported by the data. The randomizable results reinforce those of the randomized group with respect to the comparison of medical versus surgical therapy. The 10 year survival rate was similar for patients with one and two vessel coronary disease stratified by ejection fraction and for patients with three vessel coronary disease whose ejection fraction was ≥0.50 (Table 4).

The only two subgroups for which there is a significant surgical advantage are: 1) patients with proximal left anterior descending coronary artery stenosis ≥70% and an ejection fraction <0.50, and 2) those with three vessel coronary artery disease and an ejection fraction <0.50. In both of these groups (randomized and randomizable pa-

Table 3. Ten Year Actuarial Survival in the Surgical Group*

Group	Randomized			Randomizable	
	No.	Survival (%)	CABG (%)	No.	Survival (%)
CCS I–II, EF ≥0.50	260	82 ± 5	92	399	85 ± 4
CCS I–II, EF <0.50	52	80 ± 12	94	100	70 ± 10
Asymptomatic post-MI	78	81 ± 9	95	71	81 ± 10
EF <0.50	78	79 ± 9	96	85	71 ± 10
1 VD, EF <0.50	8	88 ± 23	100	7	71 ± 34
2 VD, EF <0.50	28	82 ± 14	100	25	75 ± 18
3 VD, EF <0.50	42	75 ± 14	95	53	69 ± 13
EF ≥ 0.50	291	83 ± 4	92	361	84 ± 4
1 VD, EF ≥ 0.50	95	87 ± 7	85	88	94 ± 5
2 VD, EF ≥ 0.50	126	84 ± 7	94	123	85 ± 7
3 VD, EF ≥ 0.50	70	78 ± 10	98	150	77 ± 7
1 VD, proximal LAD stenosis ≥70%	20	95 ± 10	80	51	94 ± 7
2 VD, proximal LAD stenosis ≥70%	48	81 ± 11	96	83	88 ± 7
3 VD, proximal LAD stenosis ≥70%	60	71 ± 12	100	129	77 ± 8
Total group	390	82 ± 4	93	570	81 ± 3

*$p > 0.10$ for all survival comparisons between randomized and randomizable patients. Abbreviations as in Tables 1 and 2.

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Table 4. Cox Regression Analysis ($p = 0.05$)

	No. of Cases	No. of Deaths	Variable	Relative Risk	p Value
EF >0.50					
All	1,352	203	Previous MI	1.468	0.0002
			Smoker	1.575	0.002
			Age	1.028	0.007
			LMCA	1.013	0.004
			Gender	1.523	0.042
			Group*	0.913	0.523
1 VD	474	55	Previous MI	2.074	0.0004
			Smoker	1.879	0.020
			Gender	1.922	0.048
			Group	0.675	0.149
2 VD	490	70	Group	0.842	0.473
3 VD	388	78	Gender	2.903	0.002
			Group	1.206	0.424
EF <0.50					
All	342	111	Left ventricular score	1.157	<0.0001
			Therapy	0.514	0.001
			Age	1.034	0.010
			Group	1.219	0.304
1 VD	50	19	Left ventricular score	1.336	0.002
			Group	1.528	0.394
2 VD	129	36	Group	0.089	0.798
3 VD	163	56	Left ventricular score	1.125	0.006
			Age	1.043	0.026
			Therapy	0.562	0.032
			Group	1.248	0.410
Proximal LAD disease present					
All	692	147	Previous MI	1.567	0.001
			Therapy	0.601	0.003
			Age	1.032	0.009
			Diabetes	1.664	0.025
			Smoker	1.517	0.018
			LMCA	1.012	0.017
			Left ventricular score	1.054	0.050
			Group	0.799	0.186
EF ≥ 0.50	437	72	LMCA	1.021	0.001
			Previous MI	1.629	0.006
			Age	1.051	0.006
			Smoker	1.668	0.041
			Group	0.640	0.060
EF <0.50	124	45	Therapy	0.336	0.001
			CCS	1.327	0.018
			Group	0.950	0.868
Proximal LAD disease absent					
All	1,301	225	Left ventricular score	1.120	<0.0001
			Smoker	1.809	<0.0001
			Age	1.032	0.001
			Previous MI	1.313	0.011
			Hypertension	1.350	0.032
			Group	1.176	0.239
EF ≥0.50	888	126	Smoker	1.552	0.014
			Previous MI	1.351	0.020
			Group	1.117	0.540
EF <0.50	211	64	Left ventricular score	1.176	0.0001
			Age	1.035	0.047
			Group	1.360	0.225
EF <0.50 and 3 VD	79	26	Age	1.078	0.017
			Left ventricular score	1.156	0.017
			Group	1.431	0.381

*Group = randomized/randomizable. Abbreviations as in Tables 1 and 2.

tients), coronary bypass surgery had a statistically significant beneficial effect on survival ($p < 0.05$). The reduction in the mortality rate as a result of surgery is 66% for the former group and 44% for the group with three vessel coronary disease. Further stratification of the proximal left anterior descending artery variable was not performed because of insufficient power to test statistical differences. When Cox analysis of the combined randomized and randomizable surgical group was applied including internal mammary artery conduit as a covariate, the use of the arterial conduit was associated with a reduction in the relative mortality risk of 0.554 (confidence interval 0.319 to 0.964).

Discussion

After a decade of follow-up study, there are no substantial or statistically significant differences in any of the survival comparisons between the CASS medical randomized and randomizable patients or between the surgical randomized and randomizable patients. The data confirm earlier observations (1,3,14) that survival after coronary bypass grafting is improved compared with an initial medical strategy in patients who have three vessel coronary disease and an ejection fraction <0.50, although the difference is less marked at 10 years ($p = 0.08$). Ten year survival rates are similar in medically and surgically assigned patients with less extensive coronary artery disease or those with three vessel coronary disease and an ejection fraction ≥0.50 (1).

Baseline characteristics. Detailed baseline clinical and angiographic descriptors permit an examination of the patient pool from which the randomized patients were selected. There are differences between baseline characteristics of the randomized and randomizable patients when examined in the aggregate (Table 1), illustrating that a greater proportion of the randomized patients were cigarette smokers and had hypertension and diabetes. In addition, the randomized cohort was less likely to have single vessel coronary disease, proximal left coronary artery disease or a normal ejection fraction. Thus, although the differences are small, the randomized patient on the average had a worse atherosclerotic risk profile, poorer left ventricular function, a similar extent of multivessel coronary disease and slightly less frequent proximal left coronary artery disease. We cannot rule out the possibility that there are differences in unmeasured variables between the two groups that might be important, even though we selected baseline variables known to be important from previous data (11,12). In CASS patients, analysis of therapeutic effect has always been reported on the basis of clinical, anatomic and functional subgroups.

Impact of group assignment. A major question is whether any differences between the randomized and randomizable groups have an impact on survival in terms of the overall conclusions of the CASS. We addressed the issue of the effect of group assignment after adjustment for important prognostic covariates on the overall conclusions of the CASS by treating the randomized and randomizable patients as one larger group of subjects under observation. We included the group assignment as a covariate. Group assignment refers to whether the patient is in the randomized or randomizable group. This important indicator variable adjusts for other potentially prognostic factors that might have gone unmeasured but were used by the physician to determine whether or not an individual would be randomized. The adjustment for covariates is also important because it partly answers the question as to whether the results would have been different in the randomizable group because they had more or less severe disease or a different mix of disease categories (that is, comparing surgery and medicine after adjustment for possible differences in the severity of disease in the surgically or medically treated patients). When this was done, overall (that is, for the entire group of patients), there were no differences between medical and surgical survival rates or significant differences between medical survival rates in randomized versus randomizable patients or between surgical survival rates for randomized versus randomizable patients. Analysis by subgroup confirms the reported results of the CASS randomized trial in that the only subgroups that show statistical significance are those with a low ejection fraction, patients with three vessel coronary artery disease and those with disease of the left anterior descending coronary artery.

Clearly, the overwhelming impression from the results of the CASS randomized and randomizable groups of patients is that among these mildly symptomatic patients the survival rates of the randomized and randomizable patients who received either initial medical therapy or coronary bypass grafting are basically identical. We believe that the CASS results can be extrapolated to the larger group of patients with coronary artery disease who meet CASS entry and exclusion criteria. The CASS randomized and randomizable data should not be extrapolated to other groups of patients with coronary artery disease who do not meet these criteria.

Statistical power. The CASS had relatively few patients with a poor ejection fraction in the randomized group. Clearly, in a consecutive series of patients undergoing cardiac catheterization, patients who have marked impairment of left ventricular function and single vessel coronary disease are uncommon; in the CASS, only 19 such patients were randomized. However, in the randomizable group, we find exactly the same results; there is no improvement in the 10 year survival rate as a result of coronary bypass grafting. In fact, the surgical-medical curves are superimposable. The same holds true for patients with two vessel coronary artery disease. The statistical power to examine therapeutic differences would be greater if a larger patient sample were obtained. The evidence from our 10 year data, however, is

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that there is little difference between medical and surgical therapy in these subgroups.

Conclusions. There are no substantial or statistically significant differences in any of the survival comparisons between the CASS randomized and randomizable patients assigned to medical or surgical therapy. Even when CASS randomized and randomizable patients are considered in the aggregate (that is, as if they were one group of patients in an observational study), one would come to exactly the same conclusion as was reached on the basis of the CASS randomized trial. In essence, the CASS conclusions remain correct even after a decade of follow-up study and careful examination of the randomized and randomizable groups.

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