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The Effect of Completeness of Revascularization on Event-Free Survival at One Year in the ARTS Trial

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OBJECTIVES We sought to assess the relationship between completeness of revascularization and adverse events at one year in the ARTS (Arterial Revascularization Therapies Study) trial.

BACKGROUND There is uncertainty to what extent degree of completeness of revascularization, using up-to-date techniques, influences medium-term outcome.

METHODS After consensus between surgeon and cardiologist regarding the potential for equivalence in the completeness of revascularization, 1,205 patients with multivessel disease were randomly assigned to either bypass surgery or stent implantation. All baseline and procedural angiograms and surgical case-record forms were centrally assessed for completeness of revascularization.

RESULTS Of 1,205 patients randomized, 1,172 underwent the assigned treatment. Complete data for review were available in 1,143 patients (97.5%). Complete revascularization was achieved in 84.1% of the surgically treated patients and 70.5% of the angioplasty patients ($p < 0.001$). After one year, the stented angioplasty patients with incomplete revascularization showed a significantly lower event-free survival than stented patients with complete revascularization (i.e., freedom from death, myocardial infarction, cerebrovascular accident and repeat revascularization) (69.4% vs. 76.6%; $p < 0.05$). This difference was due to a higher incidence of subsequent bypass procedures (10.0% vs. 2.0%; $p < 0.05$). Conversely, at one year, bypass surgery patients with incomplete revascularization showed only a marginally lower event-free survival rate than those with complete revascularization (87.8% vs. 89.9%).

CONCLUSIONS Complete revascularization was more frequently accomplished by bypass surgery than by stent implantation. One year after bypass, there was no significant difference in event-free survival between surgically treated patients with complete revascularization and those with incomplete revascularization, but patients randomized to stenting with incomplete revascularization had a greater need for subsequent bypass surgery. (J Am Coll Cardiol 2002;39:559–64) © 2002 by the American College of Cardiology

Randomized clinical trials indicate that both coronary angioplasty and bypass surgery have the same outcome in terms of irreversible events, such as mortality and myocardial infarction, in patients with multivessel coronary artery disease (1,2). The main difference in outcome relates to the number of subsequent revascularizations after the index procedure, which was 30% to 45% higher in the angioplasty group at one year, as demonstrated in GABI (German Angioplasty Bypass Intervention), ERACI (Estudio Randomizado Argentino de Angioplastia vs. CIrurgia) and CABRI (Coronary Angioplasty vs. Bypass Revascularization Investigation) (3–5). After three to five years, these differences in revascularization rates remain constant (2,6,7).

Over the past few years, there have been changes in both the surgical and percutaneous techniques. The use of arterial conduits during surgical revascularization and stent implantation after balloon angioplasty have become standard treatment. In the randomized trials mentioned earlier (2–7), the intention to achieve equivalence in the completeness of revascularization was required only in RITA (Randomized Intervention Treatment of Angina), GABI and ERACI. Nevertheless, the repeat intervention rate was not lower in these trials than in those that accepted non-equivalence of revascularization. Data on subgroups with complete or incomplete revascularization have been published for the BARI (Bypass Angioplasty Revascularization Investigation) trial after five years and the CABRI trial after one year (8,9). Neither BARI nor CABRI aimed at equivalent revascularization, nor did they evaluate the completeness of revascularization in the cohorts randomized to surgery.

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Abbreviations and Acronyms

ARTS = Arterial Revascularization Therapies Study
LAD = left anterior descending coronary artery
LCx = left circumflex coronary artery
RCA = right coronary artery

This report compares the differences in outcome in the ARTS (Arterial Revascularization Therapies Study) trial of bypass surgery versus percutaneous intervention between subgroups that were completely or incompletely revascularized, according to a central assessment of angiograms before bypass surgery and before and after percutaneous intervention. The general results of the ARTS trial have recently been published (10).

METHODS

Patients. Patients were eligible for the ARTS trial if they had stable or unstable angina or objective signs of ischemia and multivessel disease, defined as at least two territories of myocardium subtended by stenosed arteries (>50% diameter stenosis in a vessel with a reference diameter of at least 2.75 mm). After the surgeon and interventional cardiologist agreed on the potential for equivalence in the degree of completeness of revascularization with bypass surgery or stented angioplasty, and after the patients gave written, informed consent, the patients were randomly assigned to a treatment group over the telephone by the central office of the study. At least two of the three principal coronary arteries—the left anterior descending (LAD), left circumflex (LCx) or right coronary artery (RCA)—had to require revascularization. If the LCx was dominant, two or more treatable lesions situated in this artery also satisfied the inclusion criteria. Patients with previous angioplasty or bypass surgery were excluded, as were patients with left main coronary artery stenosis. A totally occluded vessel estimated to be less than one month old, on the basis of clinical history, could also be considered as a target vessel. If the total occlusion was of unknown duration or known to be present for more than one month, the patient could still be included as long as two other lesions were targeted. Conventional balloon angioplasty in vessels with >50% diameter stenosis and a reference diameter between 1.50 and 2.75 mm was acceptable as long as two other vessels were amenable to stenting. Lesion-specific criteria were not defined for acceptability in this study. Patients with a left ventricular ejection fraction <30%, previous cerebrovascular accident, recent infarction within the previous week or concomitant severe hepatic or renal disease, or those who needed additional major cardiac surgery, were excluded.

Surgical techniques for patients randomized to surgery were also standardized. The LAD and/or diagonal branches had to be revascularized using the left internal mammary artery. Other vessels had to be bypassed with venous bypass grafts.

Requirements for operators and institutions to qualify as a participant in the ARTS trial, and additional guidelines for medical treatment after either procedure, have previously been published (11).

To evaluate the completeness of revascularization, all patients initially treated according to randomization were included. All pertinent diagnostic angiograms were reviewed centrally at Cardialysis, Rotterdam, The Netherlands, by two independent, experienced cardiologists (Drs. van den Brand and Rensing). The coronary arteries were subdivided into 15 segments according to the American Heart Association/American College of Cardiology (AHA/ACC) criteria (12). All lesions occupying >50% diameter of a segment with a reference diameter of ≥1.50 mm were scored as potentially amenable to treatment. If all such defined segments had been treated according to the surgical report on the case-record form, the surgical procedure was scored as a complete revascularization. If one or more segments were left unbypassed, the patient was considered to be incompletely revascularized. Any patient with grafts bypassing one or more non-significant lesions and all significant lesions was included in the completely revascularized subgroup. Finally, patients treated with grafts bypassing non-significant lesions, who also had significant lesions that were left untreated, were considered to be incompletely revascularized.

For patients randomized to stented angioplasty, both the diagnostic and procedural angiograms were reviewed. The procedure was considered to result in complete revascularization if all lesions of >50% diameter stenosis had been successfully treated. If no attempt was made to treat one or more significant lesions, or if treatment resulted in a final diameter stenosis >50%, these patients were considered to be incompletely revascularized.

The degree of incompleteness of revascularization with either technique was further specified by dividing coronary artery segments into main and side branches. The proximal LAD (segments 6 and 7), proximal LCx (segment 11 and, in case of left dominance, segment 13) and proximal RCA (segments 1, 2 and 3) were scored as main branches. All other segments were scored as side branches (12). The completeness of revascularization was then scored for the main branches, the side branches or a combination of such defined vessels.

The primary end point was freedom from any of the following major adverse cardiac or cerebrovascular events: death from any cause; cerebrovascular accident; documented non-fatal myocardial infarction; and any revascularization after the index procedure. For this substudy, events were counted beginning at the index procedure.

Statistical analysis. Continuous variables were expressed as the mean value ± SD and were compared using the unpaired Student *t* test. The Fisher exact test was used for categorical variables. The Wilcoxon scores were used for categorical variables, with an ordinal scale. Discrete variables were expressed as counts and percentages and com-

Table 1. Baseline Demographics and Patient Characteristics Included in the Assessment of Complete or Incomplete Revascularization

	CABG		PTCA/Stenting	
	Complete (n = 477)	Incomplete (n = 90)	Complete (n = 406)	Incomplete (n = 170)
Gender, male	76.9%	68.9%	76.1%	79.4%
Age (yrs)	61 ± 9	62 ± 10	61 ± 10	61 ± 10
Stable angina	58.7%	58.9%	57.1%	55.9%
Unstable angina	36.3%	38.9%	36.5%	40.0%
Previous infarct	42.8%	36.7%	44.6%	42.9%
Diabetes	15.1%	23.3%*	17.7%	19.4%

*p = 0.06. Data are presented as the percentage of patients or mean value ± SD.
CABG = coronary artery bypass graft surgery; PTCA = percutaneous transluminal coronary angioplasty.

pared in terms of relative risks with 95% confidence intervals, calculated by the formula of Greenland and Robins (13). All statistical tests were two-tailed. Event-free survival was calculated according to the Kaplan-Meier method, and differences were assessed using the log-rank test.

RESULTS

Between April 1997 and June 1998, 1,205 patients were randomly assigned to stented angioplasty (n = 600) or bypass surgery (n = 605) at 67 participating centers.

Excluding patients who died while on the waiting list (n = 3), received medical treatment only (n = 5) or crossed over to the opposite treatment (n = 25), a total of 1,172 patients were treated according to their assigned procedure: 593 stented angioplasty and 579 bypass patients. Angiograms from 1,143 patients (97.5%) were available for central analysis. For stented angioplasty, 576 (97.1%) of 593 angiograms could be reviewed, whereas for bypass surgery, 567 (97.9%) of 579 angiograms were available.

Baseline demographic data and patient characteristics for subjects included in the analysis of complete and incomplete revascularizations are summarized in Table 1. Complete revascularization was achieved in 84.1% of bypass surgery patients and in 70.5% of stented angioplasty patients ($p < 0.001$). Incompletely revascularized patients from both groups showed a significantly higher number of diseased vessels and segments, compared with completely revascularized patients (Table 2).

The number of segments treated in the groups that were incompletely revascularized was lower than the number of diseased segments, as scored on the case-record forms, and even lower when compared with the angiographic assessment by the core laboratory. Some segments were left untreated because they were not scored as containing angiographically severe lesions by the investigators. According to the case-record form, the number of segments treated in the surgical group was not significantly different for the complete and incomplete revascularization groups (Table 2). For the stented angioplasty group, however, the number of (successfully) treated segments, according to the central reading of the angiograms, was significantly lower in the incompletely revascularized group (Table 2).

Table 3 summarizes the major adverse events, in rank order, for the four subgroups. A significantly higher rate of event-free survival could be demonstrated only for the completely versus the incompletely stented patients, due to a significantly lower number of subsequent bypass operations.

On average, 1.4 lesions in patients from the incompletely stented group were left untouched (66%) or resulted in a failure (34%). This is significantly higher than the average of 1.1 segments left untreated by the surgeon ($p < 0.05$). In addition, more main branches were left untouched or were unsuccessfully dilated in the incompletely stented group compared with the incompletely bypassed group (Table 4).

No differences in infarct-free and stroke-free survival could be demonstrated among the four groups (Fig. 1A). When repeat revascularizations were also considered, a significant difference in event-free survival could be demonstrated between completely and incompletely revascular-

Table 2. Extent of Coronary Artery Disease and Subsequent Treatment According to the CRF and the Angiographic ACL

	CABG		PTCA/Stenting	
	Complete	Incomplete	Complete	Incomplete
Vessels diseased per CRF	2.3 ± 0.5	2.5 ± 0.5*	2.3 ± 0.5	2.4 ± 0.5†
Vessels diseased per AACL	2.3 ± 0.5	2.7 ± 0.5*	2.2 ± 0.4	2.5 ± 0.5*
Segments diseased per CRF	2.7 ± 0.9	3.1 ± 1.1*	2.8 ± 1.0	2.9 ± 1.0
Segments diseased per AACL	2.6 ± 0.8	3.7 ± 1.1*	2.5 ± 0.6	3.4 ± 1.1*
Patients with ≥1 total occlusions	12.4%	26.7%*	5.4%	19.4%*
Segments treated per CRF	2.8 ± 0.8	2.6 ± 0.8	2.6 ± 0.9	2.3 ± 1.0*
Segments successfully treated per AACL			2.5 ± 0.6	2.0 ± 0.7*

*p ≤ 0.001 incomplete vs. complete. †p ≤ 0.01 incomplete vs. complete. Data are presented as the mean value ± SD or percentage of patients.
AACL = angiographic assessment by the core laboratory; CRF = case record form. Rest of abbreviations as in Table 1.

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Table 3. Worst Major Adverse Events, in Ranking Order, and Event-Free Survival for the Four Subgroups at One Year

	CABG		PTCA/Stenting	
	Complete (n = 477)	Incomplete (n = 90)	Complete (n = 406)	Incomplete (n = 170)
Death	12 (2.5%)	4 (4.4%)	7 (1.7%)	6 (3.5%)
CVA	9 (1.9%)	0	7 (1.7%)	2 (1.2%
MI	16 (3.4%)	4 (4.4%)	20 (4.9%)	10 (5.9%)
Q-wave	16 (3.4%)	4 (4.4%)	17 (4.2%)	9 (5.3%)
Non–Q-wave	0	0	3 (0.7%)	1 (0.6%)
Repeat CABG	1 (0.2%)	1 (1.1%)	8 (2.0%)	17 (10.0%)*
Repeat PTCA	10 (2.1%)	2 (2.2%)	53 (13.1%)	17 (10.0%)
No MACCE	429 (89.9%)	79 (87.8%)	311 (76.6%)	118 (69.4%)*

*$p < 0.05$ PTCA/stenting incomplete vs. PTCA stenting complete. Data are presented as the number (%) of patients.
CVA = cerebrovascular accident; MI = myocardial infarction; MACCE = major adverse cardiovascular or cerebrovascular events; other abbreviations as in Table 1.

ized patients from the stented angioplasty group, as well as between the stented angioplasty groups and both surgical groups (Fig. 1B). Overall, superior major adverse cardiovascular or cerebrovascular events-free survival was evident after bypass surgery, whether complete or incomplete, compared with both complete and incomplete stented angioplasty.

DISCUSSION

Incomplete revascularization is known to have a negative influence on the outcome after bypass surgery (14–17). After percutaneous angioplasty, this adverse relationship is much less clear (18–27). There may be several reasons for this discrepancy, including the definition and assessment of completeness of revascularization, the patients studied and the duration of follow-up. If the usual definition for completeness of revascularization is applied to the stented angioplasty patients (25), complete revascularization was present in 70% of the stented angioplasty patients. This compares favorably with previous reports on the completeness of percutaneous revascularization in two other randomized trials of angioplasty versus surgery (8,9), but it was nevertheless somewhat disappointing for modern-day percutaneous coronary interventions.

Comparison and assessment of completeness of revascularization. In the BARI trial, complete revascularization was attempted in only 584 (64%) of 907 patients randomized to angioplasty, but the percentage of patients who were actually completely revascularized is not mentioned. In CABRI, only 29% of all angioplasty patients had complete revascularization (9). In contrast to the ARTS trial, BARI and CABRI did not aim to achieve equivalency in the degree of completeness of revascularization in both patient groups. At five years in BARI, this led to a non-significant

Table 4. Extent and Quality of Incompleteness in Both Groups Treated With Bypass Operation or Stented Angioplasty Assessed by the ACL

	CABG (n = 90)	PTCA/Stenting (n = 170)
Diseased vessels, average	2.7 ± 0.5	2.5 ± 0.5
Diseased segments, average	3.7 ± 1.1	3.4 ± 1.1
Successfully treated segments, average	2.6 ± 0.8	2.0 ± 0.7*
Untreated segments*		
Main branch only	24 (27%)	60 (35%)
Side branches only	63 (70%)	85 (50%)
Main and side branches	3 (3%)	25 (15%)

*$p < 0.01$ PTCA/stenting vs. CABG. Data are presented as the mean value ± SD or number (%) of patients.
Abbreviations as in Tables 1 and 2.

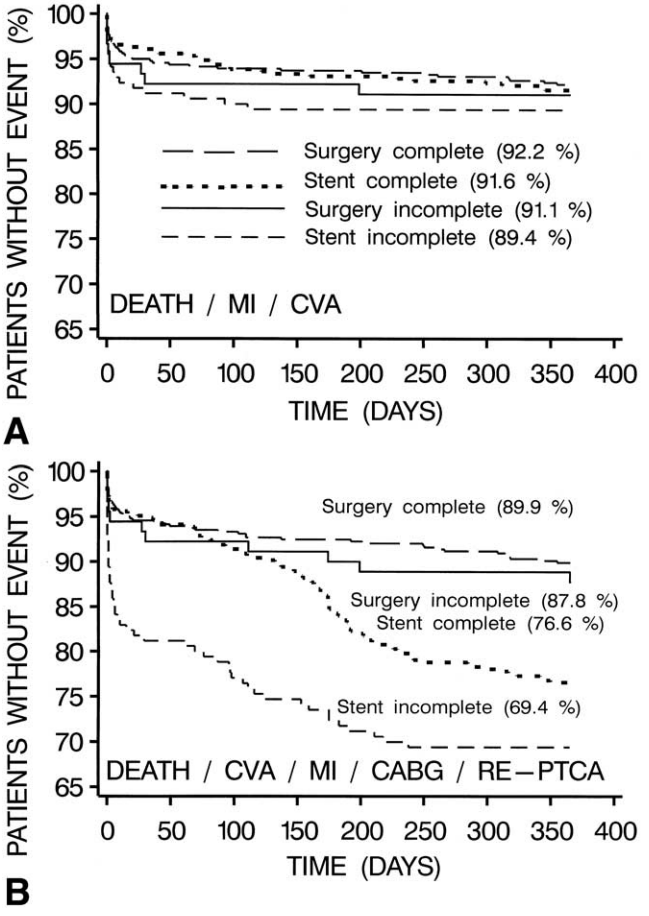

Figure 1. (A) Freedom from death, myocardial infarction (MI) or cerebrovascular accident (CVA) within one year, after complete or incomplete revascularization with coronary artery bypass graft surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA) stenting. **(B)** Event-free survival in the four subgroups, also including repeat revascularization as an event.

difference in mortality of 4.6% between surgically treated patients and incompletely revascularized angioplasty patients, compared with a mortality difference of 1.1% between surgically treated patients and those with intended complete revascularization by angioplasty. The only other difference that approached significance was the percentage of patients undergoing bypass surgery within five years after angioplasty, which was 29.7% versus 36% for those with planned complete versus incomplete revascularization.

In the CABRI angioplasty cohort, after one year, the completely revascularized patients had a higher event-free survival, compared with incompletely revascularized patients (69% vs. 57%; $p = 0.01$). The same trend toward a higher mortality rate exists for incompletely revascularized patients in the ARTS trial, in both the stented angioplasty and surgically treated groups. Although our study extends to only one-year follow-up, the difference in event-free survival was already present at hospital discharge after the initial procedure. In fact, two-thirds of all bypass operations after an incomplete angioplasty procedure were performed during the initial hospital stay.

Assessment of the completeness of revascularization may be an important issue. Generally, all bypass operations are considered by the surgeon to be complete, but early closure of a certain percentage of bypass grafts is well documented. Thus, revascularization by 30 days after the procedure may not be as complete as assumed by the surgeon at the time of the operation. Angioplasty, by its very nature, is easier to evaluate critically with respect to the completeness of revascularization. Incomplete revascularization may be due to lesions that are not amenable to angioplasty (e.g., totally occluded small branches with adverse characteristics), but it may also be due to a generous interpretation of the post-procedural angiogram by the operator. It is well known that assessment of procedures by core laboratories not directly involved with patient enrollment may lead to outcome scores different from those reported by the operator (28,29). For example, in the GUSTO-IIb (Global Use of Strategies To Open occluded arteries in acute coronary syndromes) study, the core laboratory scored an additional 14% of procedures as being unsuccessful, because at the end of the intervention, the lesion severity still exceeded the 50% diameter stenosis criterion.

In this study, when all of the diagnostic angiograms of the patients randomized to surgery or stented angioplasty were read centrally, many patients were scored as being incompletely revascularized. This assessment for surgical patients was done by comparing the diagnostic angiogram score with the investigator's surgical procedure report. For stented angioplasty patients, the assessment of the completeness of revascularization was achieved by comparing the diagnostic angiogram with the post-procedural angiogram. This provided a much more stringent evaluation of the completeness of revascularization than that in the surgical group. Thus, accurate and reliable scoring of the completeness of surgical revascularization cannot be guaranteed, because only repeat angiography of all patients immediately after surgery can provide such information, and this would be very difficult to justify.

Patient selection. Incompletely revascularized stented patients showed more extensive coronary artery disease than the completely revascularized angioplasty patients in ARTS. In BARI, this difference in significantly diseased segments was 3.9 versus 3.2, and in our study, it was 3.4 versus 2.5, according to the core laboratory reading (8). In addition, the number of patients with at least one totally occluded segment was 30% higher in the incompletely revascularized group in BARI. In our study, the total number of patients with at least one total occlusion was much lower than that in BARI, reflecting the intention of complete and comparable revascularization in ARTS for the surgery and stented angioplasty groups. Nevertheless, in our study, the frequency of totally occluded segments was 14% higher in the incompletely revascularized groups. Thus, both the more extensive coronary artery disease and the higher percentage of totally occluded segments contribute to a lower percentage of patients with complete revascularization. Unexpectedly, this was also true for patients treated with bypass surgery.

Duration of follow-up. One of the shortcomings of our study is the relatively short duration (one year) of follow-up. Nevertheless, most events after angioplasty occur in the first year, and a significant difference in event-free survival was obvious between completely and incompletely revascularized patients in the stented angioplasty group. With a comparable gender mix and age distribution of patients studied in BARI and ARTS, and a higher percentage of diabetic and unstable patients in BARI—but with similar left ventricular function, the "natural" history without intervention might be expected to be comparable for patients enrolled in these two studies. Nevertheless, the difference in the incidence of bypass surgery procedures after complete angioplasty in the two studies is striking: 2% in ARTS after one year and 29.7% in BARI after five years.

Part of this difference in the repeat intervention rate can undoubtedly be ascribed to a reduction in restenosis by the implantation of stents in the ARTS trial (in 89% of all dilated lesions). The number of repeat angioplasties constituted 13.1% in ARTS within one year, 24.1% in BARI within five years and 21.6% in CABRI within one year (2,5). Progression of atherosclerosis between one and five years was an important reason for subsequent bypass surgery in BARI, possibly coupled with a greater tendency to opt for surgery as opposed to repeat angioplasty with stenting in 1995. Further developments in anti-restenosis therapy (e.g., brachytherapy, drug-eluting stents) may offer continued percutaneous options in patients with restenosis or in-stent restenosis after initially successful percutaneous procedures, so that bypass surgery is no longer the only option available to such patients.

Conclusions. The design of the ARTS trial was such that at least two lesions in arteries >2.75 mm, leading to two

different territories, had to be treated. Despite intentional comparable revascularization, completeness was achieved in 84.1% of bypass patients and 70.5% of stented angioplasty patients, according to a central angiographic core laboratory assessment. After one year, this led to 7% and 2% lower event-free survival rates for incompletely revascularized patients from the stented angioplasty and surgically treated cohorts, respectively, when compared with completely revascularized patients allocated to the same treatment. This means that for angioplasty patients, the effectiveness and cost-effectiveness can be further enhanced by careful selection of patients, making complete revascularization the aim and the outcome of the procedure.

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