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Long-Term Outcomes Following Bilateral vs Single Internal Thoracic Artery Grafts

A Secondary Analysis of a Randomized Clinical Trial

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IMPORTANCE Bilateral internal thoracic artery grafting has been proposed to improve survival compared to standard single internal thoracic artery grafting during coronary artery bypass graft (CABG) surgery, but any survival benefit may emerge only with longer-term follow-up.

OBJECTIVE To report 15-year extended follow-up of a randomized clinical trial of bilateral vs single internal thoracic artery grafting for CABG.

DESIGN, SETTING, AND PARTICIPANTS This is a secondary analysis of an unblinded randomized clinical trial that took place at 28 cardiac surgery centers in 7 countries between June 2004 and December 2007, with 15-year follow-up reported after 2025. Patients scheduled for CABG on clinical grounds were eligible. Those requiring only single grafts or concomitant valve surgery, as well as those with a history of previous CABG, were excluded. All 3102 patients in the original trial provided data for this analysis, while 3042 completed the full 15-year follow-up. Data were analyzed from January to March 2026.

INTERVENTION If patients fulfilled all the eligibility criteria and provided written informed consent, they were randomly assigned to bilateral or single internal thoracic artery grafts with vein or radial artery grafts used in both groups as clinically indicated.

MAIN OUTCOMES AND MEASURES All-cause mortality at 15 years. The composite of all-cause mortality, myocardial infarction, or stroke was a secondary outcome.

RESULTS A total of 1548 patients were randomized to bilateral internal thoracic artery grafts and 1554 to single internal thoracic artery grafts. The mean (SD) age was 64 (9) years and 446 (15%) were female. In the bilateral graft group, 215 (14%) received only a single arterial graft, while in the single graft group, 359 (23%) also received a radial artery graft. At 15 years, vital status was known for 3039 patients (98%). There were 585 deaths (37.8%) in the bilateral graft group and 584 (37.6%) in the single graft group (hazard ratio [HR], 1.00; 95% CI, 0.89-1.12; $P = .97$). Secondary outcome event rates were 43.9% and 45.8%, respectively (HR, 0.94; 95% CI, 0.85-1.05).

CONCLUSIONS AND RELEVANCE There was no difference in all-cause mortality at 15 years between patients undergoing CABG who were randomized to bilateral vs single internal thoracic artery grafts in an intention-to-treat analysis. Given the high rate of potential postrandomization confounders (eg, crossovers and use of radial arteries), the multiple arterial graft hypothesis still needs to be tested in randomized clinical trials.

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Visual Abstract

Supplemental content

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Group Information: The Arterial Revascularization Trial investigators are listed in Supplement 3.

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Coronary artery bypass graft (CABG) surgery is one of the most common major operations and is an effective way to manage advanced coronary artery disease.[1,2] Use of the left internal thoracic artery graft, plus additional vein grafts, is the most frequent procedure used in CABG surgery. The benefits of left internal thoracic artery grafts have been well established, and these are attributed to its superior long-term patency compared to vein grafts.[3-7]

Observational studies indicate potential reductions in long-term mortality when both the left and right internal thoracic artery grafts are used for CABG compared to use of the left internal thoracic artery graft plus vein grafts where required in both groups.[8,9] The excellent long-term angiographic patency of the left and right internal thoracic artery grafts also supports the hypothesis that bilateral internal thoracic artery grafts may be associated with better clinical outcomes.[5,10]

The Arterial Revascularisation Trial (ART) randomized 3102 patients to either bilateral internal thoracic artery grafts or a standard single left internal thoracic artery graft during CABG, plus supplemental arterial or vein grafts used in both groups as considered necessary.[11] The primary analysis[12] at 10 years of follow-up showed no significant differences between the 2 strategies for all-cause mortality or the composite of all-cause mortality, myocardial infarction, or stroke. At 10 years, the observed event rate was lower than expected, so the trial was formally underpowered for the prespecified treatment effect. There was also a potential divergence of the survival curves for the composite outcome of all-cause mortality, myocardial infarction, or stroke at 10 years that warranted a follow-up extension. Accordingly, we report here the extended follow-up results of ART at 15 years.

Key Points

Question Do bilateral internal thoracic artery grafts provide a survival advantage at 15 years compared to single internal thoracic artery grafts in patients undergoing coronary artery bypass graft surgery (CABG)?

Findings This secondary analysis of a randomized clinical trial including 28 cardiac surgery centers and 3102 patients randomized to bilateral or single internal thoracic artery grafts during CABG found no difference in 15-year all-cause mortality between the groups.

Meaning These findings suggest that using bilateral rather than single internal thoracic artery grafts during CABG may not improve long-term survival.

Methods

Trial Design

ART was a 2-arm unblinded randomized clinical trial conducted in 28 hospitals in 7 countries between June 2004 and December 2007. Details of sites and investigators are provided in eAppendix 1 in Supplement 2, and trial steering committee members are in eAppendix 2 in Supplement 2. Previous reports including trial design, prespecified interim analyses and 10-year results (primary analysis) have been published.[12] Key details of methods are included in this report to avoid referring to multiple previous publications. Ethical approvals for the 15-year extension were obtained for all sites from their respective review boards and individual patient re-consent for the extended follow-up was not required. All participants were given the option to withdraw from the study if they wished. The protocol is in Supplement 1.

Patients, Enrollment, and Randomization

Eligible patients were those with multivessel coronary artery disease scheduled to undergo CABG (including patients requiring urgent surgery, but not those with evolving myocardial infarction). Those requiring only single grafts or concomitant valve surgery, as well as those with a history of previous CABG, were excluded. Each patient was required to provide written informed consent at the time of randomization and was given the option to opt out of the 15-year follow-up.

Surgical Procedure

The bilateral internal thoracic artery grafting group (the *bilateral graft group*) received both left and right internal thoracic artery grafts to the 2 most important left-sided coronary arteries with supplemental vein grafts or radial artery grafts to other coronary arteries as clinically indicated. In the bilateral graft group, internal thoracic artery grafts could be used as composite grafts to each other, as long as one remained in situ. Anastomosis of an internal thoracic artery graft to the right coronary artery was not permitted because of concerns of inferior long-term patency. The single internal thoracic artery grafting group (the *single graft group*) received a left internal thoracic artery graft to the left anterior descending coronary artery plus supplemental vein grafts or radial artery grafts to other coronary arteries as determined by the operating surgeon.

Outcome Measures

Consistent with the primary analysis, the primary outcome for the 15-year follow-up was all-cause mortality and the secondary outcome was the composite of all-cause mortality, myocardial infarction, or stroke (time to first event). Additional exploratory outcomes included the rate of repeat revascularization and individual components of the secondary outcome. Health economic evaluations are reported separately. Outcome definitions for 15-year follow-up are provided in eAppendix 3 in Supplement 2.

For patients recruited in England and Wales, data were gathered through the central register of deaths (National Health Service England) and Hospital Episode Statistics. Key personal identifiers were shared with patients' consent to allow matching with these national registers using previously described methods.[13] All other sites obtained data through personal contact with participants or with family physicians, use of hospital records, and central registers, where available. For the 15-year analysis, clinical outcome events did not undergo formal adjudication. The 15-year follow-up analysis had more than 70% conditional power to detect a 4% absolute

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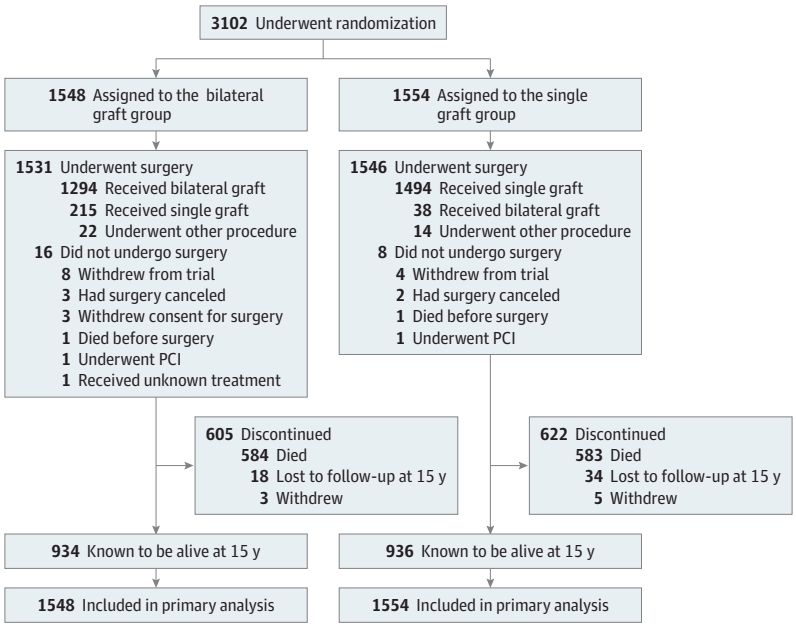
Figure 1. Participant Flow Diagram



difference (consistent with the original estimated absolute difference in all-cause mortality), with at least 95% completeness of follow-up assuming no difference at 10 years.

Statistical Analysis

This analysis censored patients at 15 years of follow-up after the date of randomization. The primary analysis used the intention-to-treat principle. For patients who had died, time from randomization to death was calculated. For those who were alive or their status was not known, the time from randomization until they were last recorded as alive was calculated. A sensitivity analysis was carried out adjusting for age, sex, ejection fraction and diabetes. Time-to-event analysis was performed using the log-rank method and Cox proportional-hazards regression to estimate hazard ratios (HRs) and 95% CIs. We used visual inspection of the curves and comparison with HRs from the 10-year analysis to assess proportionality over time. A competing-risks analysis was used when analyzing myocardial infarction, stroke, and repeat revascularization.

The ART trial was conceived to compare the effect of single vs multiple arterial grafts for CABG. When the trial was designed the clinical benefit associated with the use of the radial artery in coronary surgery and its relative superiority compared to the saphenous vein were not known, and in ART the use of the radial artery at the time of CABG was allowed based on surgeon preference.[14,15] Use of the radial artery in ART could be considered an intercurrent postrandomization event that affects the interpretation of the trial. For this reason, we prespecified analysis of ART data using the intention-to-treat approach, the per-protocol approach (including only those patients who received their randomly assigned treatment), and an as-treated analysis comparing patients who received multiple vs single arterial grafts as a hypothesis generating analysis.[16]

Prespecified subgroup analyses were performed based on baseline diagnosis of diabetes (yes/no), age (<70 years/≥70 years), female/male, off-pump/on-pump surgery, radial/nonradial graft use, ≤3/>3 grafts, ejection fraction <50%/≥50% and country (UK/other). The statistical analysis plan provides a complete description of all the planned analyses and is available in eAppendix 4 in Supplement 2. A *P* value <.05 was considered significant for the primary outcome. All other outcomes are summarized with hazard ratios and confidence intervals. Confidence intervals were not adjusted for multiplicity and therefore should not be used to infer definitive treatment effects. All analyses were performed using Stata software version 14 (StataCorp). Data were analyzed from January to March 2026.

Results

Patients

Of the 3102 patients enrolled in the trial, 1548 were randomized to the bilateral graft group and 1554 patients to the single graft group. The final censoring date for inclusion of data was February 25, 2026. **Figure 1** shows the flow of participants through the trial up to 15 years of follow-up. One patient in each group died before undergoing surgery. Information on vital status (dead or alive) was missing at the final 15-year follow-up for 63 patients (2.0%). For nonfatal secondary outcomes, outcome status was ascertained in 2947 participants (95%). The groups were well matched with respect to age, sex, race, ethnicity, body mass index, systolic and diastolic blood pressure, smoking status, and comorbidities (eTables 1 and 2 in Supplement 2).

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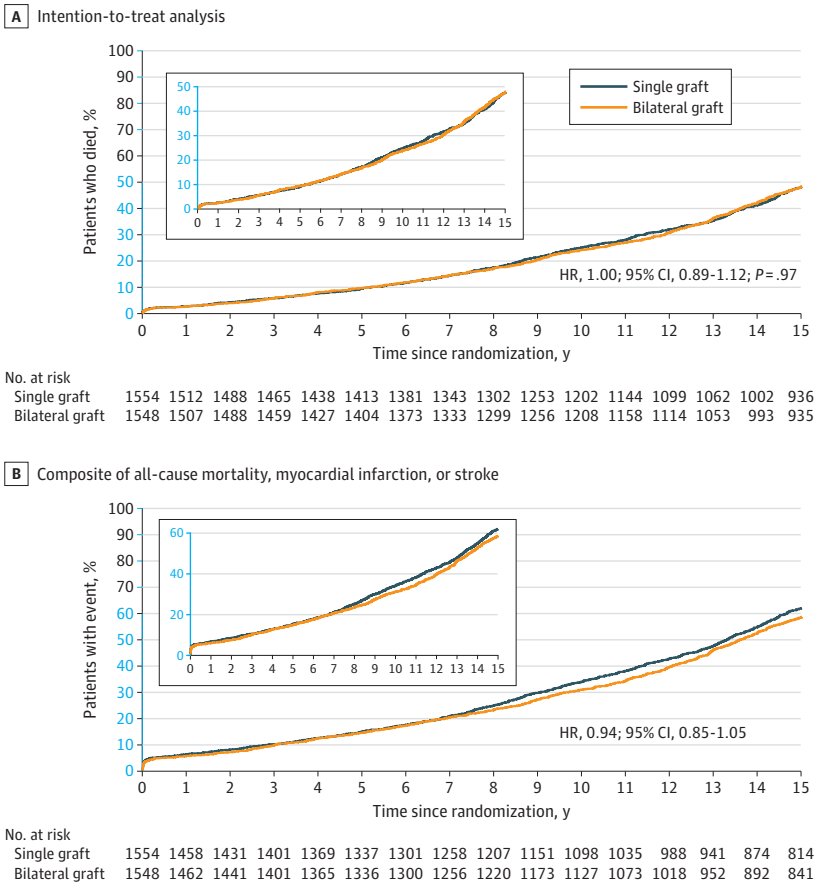
Table. Clinical Outcomes at 15 Years by Randomized Group (Intention-to-Treat Analysis)

Outcome	No. (%)			*P* value
	Bilateral graft (n = 1548)	Single graft (n = 1554)	Hazard ratio (95% CI)[a]	
All-cause mortality (primary outcome)	585 (37.8%)	584 (37.6%)	1.00 (0.89-1.12)	.97
Composite: all-cause mortality, myocardial infarction, or stroke	680 (43.9%)	711 (45.8%)	0.94 (0.85-1.05)	NA
Myocardial infarction[b]	127 (8.2%)	147 (9.5%)	0.86 (0.68-1.09)	NA
Stroke[b]	95 (6.1%)	112 (7.2%)	0.85 (0.65-1.12)	NA
Repeat revascularization[b]	223 (14.4%)	231 (14.9%)	0.97 (0.80-1.16)	NA

[a] Confidence intervals reported in this table have not been adjusted for multiple testing and therefore should not be used to infer definitive treatment effects.

[b] These rows include all of the patients with myocardial infarctions or strokes up to 15 years, not just those who form part of the composite outcome. Since death is a competing risk for myocardial infarction, stroke, and repeat revascularization, the analysis takes account of this, and therefore hazard ratio refers to a subdistribution hazard ratio for these 3 rows.

Figure 2. Kaplan-Meier Curves for All-Cause Mortality and Composite Clinical Outcomes at 15 Years



Treatment

Surgical details, hospital length of stay, and adherence to randomized allocation are provided in the previously published 10-year report[12] and in eTable 3 in Supplement 2. In the bilateral graft group, 1294 (83.6%) received bilateral internal thoracic artery grafts, while in the single graft group, 1494 (96.1%) received a single internal thoracic artery graft. Additional radial-artery grafts were used in 273 (18%) of patients in the bilateral graft group and 359 (23%) in the single graft group.

Outcomes

A total of 1169 participants (37.7%) had died by 15 years, with 585 deaths (37.8%) in the bilateral graft group and 584 (37.6%) in the single graft group (hazard ratio [HR], 1.00; 95% CI, 0.89-1.12; *P* = .97) (**Table**; **Figure 2**A). Results were similar after adjustment for age, sex, diabetes, and ejection fraction (HR, 0.99; 95% CI, 0.88-1.11).

For the composite of all-cause mortality, myocardial infarction, or stroke there were 680 patients (43.9%) with events

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in the bilateral graft group compared to 711 (45.8%) with events in the single graft group (HR, 0.94; 95% CI, 0.85-1.05) (Table; Figure 2B). Individual components of this outcome are shown in the Table, with no differences between the 2 groups. There was no difference in rates of repeat revascularization (223 [14.4%] in the bilateral graft group and 231 [14.9%] in the single graft group) (Table). Intention-to-treat analyses for the primary outcome according to clinically relevant subgroups, by country or surgeons with higher volumes, did not show any evidence of interactions (eFigures 1-3 in Supplement 2). In a post hoc sensitivity analysis incorporating a shared frailty term for operating surgeon, the treatment effect was unchanged (HR, 1.00; 95% CI, 0.89-1.12; P = .98). Although there was evidence of between-surgeon heterogeneity in baseline mortality risk, this did not materially alter the estimated treatment effect. Results for the primary outcome in the per-protocol analysis were similar to those for the intention-to-treat analysis (eTable 4 in Supplement 2).

Baseline characteristics for the as-treated analysis appeared well matched and are shown in eTable 5 in Supplement 2. There were 589 deaths among 1690 participants (34.9%) in the group with 2 or more arterial grafts vs 546 of 1330 participants (41.1%) in the group with a single internal thoracic artery graft (adjusted HR, 0.84; 95% CI, 0.75-0.95) (eFigure 4 and eTable 6 in Supplement 2). Results for the secondary outcome are shown in eFigure 5 and eTable 6 in Supplement 2.

Discussion

ART has undertaken one of the longest and most complete follow-up studies of any CABG trial, and with more than 1000 deaths, is well powered to detect even small differences between the randomized groups. The 15-year intention-to-treat analysis, however, showed no difference in all-cause mortality or the composite of all-cause mortality, myocardial infarction, or stroke between patients randomized to bilateral or single internal thoracic artery grafting.

The research question is still relevant, as CABG is one of the most common surgical operations and the hypothesis that the use of multiple arterial grafting could improve survival was first proposed more than 20 years ago, but never, to our knowledge, formally tested in a randomized clinical trial prior to ART.[17] At 10 years, the mortality rate observed in the control arm was lower than anticipated in the sample size calculation (20% vs 25%[12]), so there was potential for the trial to be underpowered for the prespecified treatment effect. There was also a potential separation of the survival curves for the composite of all-cause mortality, myocardial infarction, or stroke in favor of the bilateral internal thoracic artery group at 10 years, and a benefit over a longer period could not be excluded. The incremental value of the 15-year data compared to the 10-year data includes the longer-term follow-up (probably unique for a CABG trial) to help ensure that any late effects of arterial and venous patency are properly accounted for, increased power due to more events, and a confirmation that there is no further variation over time after 10 years in the relative outcomes between bilateral and single internal thoracic artery grafts on an intention-to-treat analysis.

The main rationale for routinely adding multiple arterial grafts during CABG is longer-term patency compared to saphenous vein grafts, which is then expected to translate into better cardiovascular outcomes compared to a single arterial graft.[15,18] In general, around 50% of vein grafts are occluded at 10 years in contrast to angiographically documented patency of around 90% for both internal thoracic artery grafts.[5,10,19] Previous nonrandomized data[19] reported clinical benefits associated with the use of bilateral vs single internal thoracic artery, with consistent treatment effect seen across countries and methodological approaches. In ART surgeons were free to use the radial artery as clinically indicated. As a result, 632 patients (273 in the bilateral graft group and 359 in the single graft group) received a radial artery, so that in 23% of the patients randomized to the single graft group a second arterial graft was used. When ART was designed, the potential clinical benefit of the radial artery in coronary surgery and its relative superiority compared to the saphenous vein were not known.[14] Therefore, use of the radial artery at the time of CABG could be considered as a postrandomization intercurrent event which could provide added benefit to the single arterial graft group, and this is the primary justification for the as-treated analysis.

Large observational studies[20,21] have repeatedly reported benefits of multiple vs single arterial grafts. In the largest analysis to date, Sabik and colleagues[22] reported on more than 1 million patients receiving single or multiple arterial grafts. At 10 years, multiple arterial grafts were associated with improved survival (adjusted HR, 0.86; 95% CI, 0.85-0.88). An analysis using the Society of Thoracic Surgeons database reported that a strategy of single internal thoracic artery plus radial artery grafting was associated with equivalent long-term survival compared to bilateral internal thoracic artery grafting. Bilateral internal thoracic artery plus radial artery was associated with further improvement in survival (oral presentation from Schwann et al at the Society of Thoracic Surgeons January 31, 2026).

The postrandomization variables that could confound the ART findings are the 14% crossover rate of patients randomized to bilateral internal thoracic artery grafts, but who in fact received only a single arterial graft, and the use of the radial artery in about one-fifth of all patients. Both aspects likely provide an advantage for the single graft group. Other factors may also influence the findings, including surgeon expertise and volume. Other potential issues include the heterogeneity of health care systems and local resources in centers from 4 continents and variation in the surgical method of achieving bilateral internal thoracic artery grafting. The influence of systematic differences in postrandomization variables is notoriously difficult to quantify but the potential benefit of multiple arterial grafts compared to a single internal thoracic artery graft has been a consistent finding from exploratory analyses in ART,[21] in a meta-analysis of randomized clinical trials of radial artery vs no radial artery trials,[14] and well-designed observational studies.[22-25]

Our own as-treated analysis presented here, as well as the many observational studies, may exaggerate the benefits of

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multiple arterial grafts compared to a single arterial graft due to inherent biases in these nonrandomized comparisons. Although not yet certain, the influence of improved vein graft surgical techniques, better longer-term patency of vein grafts, and more consistent use of preventive medication like statins and aspirin may narrow the gap in longevity and effectiveness between arterial and vein grafts.[26] Although no differences in clinical outcomes were observed, ART has demonstrated the safety of bilateral internal thoracic artery grafting in a wide range of surgical centers. The findings from the multiple vs single arterial graft analysis, as well as subgroup analysis by country and surgeon, suggest that there may be important operative, center, patient, and surgeon effects that could lead to improved outcomes with a more selective approach to the use of multiple arterial grafts. Rates of repeat revascularization were not different in the intention-to-treat analysis but were numerically greater in the single arterial group in the as-treated analysis, suggesting that there may also be higher rates of symptomatic angina in the latter group. Several of these issues are likely to be answered in the ongoing Randomized Comparison of the Clinical Outcome of Single vs Multiple Arterial Grafts (ROMA) trial which has randomized more than 4000 patients.[27,28]

Limitations

There are limitations to be noted. The as-treated analysis is a nonrandomized comparison with all the associated limitations of this approach, including baseline imbalances between groups and potential bias in the assignment of multiple vs single arterial grafts, and therefore any findings should be interpreted with caution. Other limitations for the study overall include potential biases associated with an open study where clinicians and patients know the treatment allocations, nonadherence to randomized allocation, use of the radial artery, and missing data. Secondary outcomes were ascertained in different ways, including use of central registries, health records, and direct contact with the patient, which could lead to heterogeneity of outcomes but is unlikely to introduce systematic bias in this randomized trial. Events from 10 to 15 years of follow-up were not independently adjudicated, and this limitation meant that we were not able to provide data on cause of death (for example cardiovascular/noncardiovascular) or type of repeat revascularization (percutaneous coronary intervention or CABG). This may impact the quality and consistency of event ascertainment, especially for nonfatal outcomes.

Conclusions

ART found that there was no difference in all-cause mortality at 15 years in patients undergoing CABG between bilateral and single internal thoracic artery grafts in the intention-to-treat analysis. The high crossover rates and liberal use of radial artery grafts in this open trial could have caused postrandomization confounding, and therefore further randomized trials are needed to determine if multiple arterial grafts provide better outcomes than a single internal thoracic artery graft for patients undergoing CABG.

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