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Outcomes following revascularization with radial artery bypass grafts: Insights from the PREVENT-IV Trial

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Abstract

Background—The optimal role of radial artery grafts in coronary artery bypass grafting (CABG) remains uncertain. The purpose of this study was to examine angiographic and clinical outcomes following CABG among patients who received a radial artery graft.

Methods—Patients in the angiographic cohort of the PREVENT-IV trial were stratified based upon having received a radial artery graft or not during CABG. Baseline characteristics and 1-year angiographic and 5-year clinical outcomes were compared between patients.

Results—Of 1,923 patients in the angiographic cohort of PREVENT-IV, 117 received a radial artery graft. These patients had longer surgeries (median 253 vs 228 minutes, $p < 0.001$) and had a greater number of grafts placed ($p < 0.0001$). Radial artery grafts had a graft-level failure rate of 23.0%, which was similar to vein grafts (25.2%) and higher than LIMA grafts (8.3%). The hazard of the composite clinical outcome of death, MI, or repeat revascularization was similar for both

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cohorts (adjusted HR 0.896, 95% CI 0.609–1.319, $p=0.58$). Radial graft failure rates were higher when used to bypass moderately stenotic lesions (<75% stenosis, 37% failure) compared with severely stenotic lesions (≥75% stenosis, 15% failure).

Conclusions—Radial artery grafts had early failure rates comparable to saphenous vein and higher than LIMA grafts. Use of a radial graft was not associated with a different rate of death, MI, or postoperative revascularization. Despite the significant potential for residual confounding associated with post hoc observational analyses of clinical trial data, these findings suggest that when clinical circumstances permit, the radial artery is an acceptable alternative to saphenous vein and should be used to bypass severely stenotic target vessels.

Keywords

coronary artery bypass grafting; radial artery; revascularization

Introduction

Multiple studies have demonstrated higher rates of graft patency associated with internal mammary artery (IMA) grafting compared with venous grafts, which has resulted in the preferred usage of this conduit, particularly when revascularizing the left anterior descending (LAD) artery^{1–3}. Venous grafts are associated with significantly higher rates of graft failure as well as the need for subsequent revascularization procedures and death from major adverse cardiac events (MACE)^{4–6}. The optimal role of the radial artery as a conduit in CABG remains less well elucidated. Most studies, including several randomized controlled trials, have demonstrated graft failure rates of radial artery conduits between those of IMA and venous grafts^{7–9}. Therefore, some advocate for using the radial artery as a second or third arterial graft prior to utilizing saphenous vein¹⁰. The results of these studies are not entirely consistent and further investigation is warranted¹¹. The purpose of this study was to characterize the cohort of patients undergoing CABG with radial artery grafts and describe their associated angiographic and clinical outcomes using data collected in the Project of Ex-vivo Vein Graft Engineering via Transfection (PREVENT) IV trial^{12,13}. We further sought to identify patient and graft factors at the time of revascularization associated with subsequent radial graft failure.

Methods

This study is a post-hoc analysis of the PREVENT-IV trial, the design and results of which have been previously reported^{12–14}. Briefly, PREVENT-IV enrolled patients age 18–80 undergoing a first isolated CABG with at least two planned vein grafts from 2002 to 2003 at 107 US sites. Use of arterial grafts, including IMA and radial artery grafts, were left to the discretion of the surgeon. This study included patients in the angiographic cohort that returned for scheduled coronary angiography 12–18 months after their index surgery. Patients were stratified into two groups: those that had undergone revascularization using a radial artery conduit and those that did not. All aspects of radial artery use including target vessel selection were at the discretion of the operating surgeon. Radial versus non-radial group status was determined irrespective of other grafts used. A subanalysis was performed

among the radial artery group, with patients stratified by the occurrence of radial graft failure on angiographic follow up.

The primary outcome was graft failure, defined as graft stenosis >75% at 12–18 month angiographic follow up. Clinical endpoints included rates of death, myocardial infarction (MI), and revascularization and a composite of these three outcomes over 5 years. Repeat revascularization was defined as repeat CABG or percutaneous coronary intervention (PCI) within the follow-up period.

Baseline demographic and clinical characteristics were presented as median (25th – 75th percentiles) for continuous variables and count (%) for categorical variables, unless otherwise specified. Comparisons between radial and non-radial groups were performed using the Wilcoxon rank sum test for continuous variables and the Pearson χ^2 test or Fisher's exact test for categorical variables.

Rates of graft failure were expressed as raw frequencies. The denominator for graft specific rates is the number of grafts in each group of that type. The denominator for overall graft failure is the number of patients in each group. A generalized estimating equation (GEE) was used to compare overall graft failure (graft level) between the groups to account for within-patient correlation. A graft failure sensitivity analysis was performed defining graft failure as complete occlusion at angiographic follow up.

Rates of major adverse cardiac events (MACE) including death, MI, and repeat revascularization were computed as the number of events per 100 patient-years of follow-up. The association between radial usage and clinical outcomes was assessed using unadjusted Cox proportional hazards models. Because of the small sample size in the radial graft group, an adjusted Cox proportional hazards model was only performed for the composite endpoint of MACE. Adjustment variables included age, gender and history of congestive heart failure. The proportional hazards assumption was tested and not grossly violated for any outcome. Results were expressed as incidence rates, hazard ratios (with 95% confidence intervals), and associated p-values.

Two-sided p-values ≤ 0.05 were considered statistically significant unless otherwise indicated. All statistical analyses were performed by statisticians at the Duke Clinical Research Institute (Duke University, Durham, NC) using SAS version 9.4 (SAS Institute, Inc., Cary, NC). Funding for this study was provided by NIH grant 5T32HL069749 and the Duke Clinical Research Institute (DCRI). The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents.

Results

In total, 1,923 patients met inclusion criteria including 117 patients who underwent CABG with at least one radial artery graft and 1,806 patients who underwent CABG without a radial artery graft. Radial artery grafting was performed at 37 of the 107 PREVENT-IV sites (Supplemental Figure 1). Median follow-up time for angiography was 384 days (IQR 371–409). Baseline demographic and clinical characteristics of the study population are

summarized in Table 1. Patients who received a radial artery graft were younger (median age 56 vs 64, $p<0.001$), more likely to be male (94.9% vs 79.8%, $p<0.001$), and less likely to have a history of congestive heart failure (2.6% vs 7.9%, $p=0.034$).

Patients who underwent CABG with a radial artery conduit had a greater average number of grafts placed (4.1 vs 3.3), were more likely to have received a LIMA graft (86.3% vs 79.8%), had longer surgeries (median procedure length 253 vs 228 minutes, $p<0.001$) including longer times on cardiopulmonary bypass (median 110.5 vs 99.0 minutes, $p<0.001$) (Table 1). They had shorter ICU stays (median 23 hours vs 26 hours, $p=0.002$), similar post-operative ventilation requirements (median 7 hours vs 7 hours, $p = 0.475$), and similar overall hospital length of stay (median 6 days vs 6 days, $p=0.858$).

Rates of graft failure on 12–18 month angiographic follow-up are summarized in Table 2. Radial artery graft failure occurred in 23% of grafts. This was higher than the rate of LIMA failure and similar to the rates of vein and RIMA failure. The overall rate of graft failure rate was similar in patients with and without radial grafts (24% vs 21%, $p=0.14$). On the patient-level, those who had a radial artery graft were more likely to experience failure of any graft than patients who did not receive a radial artery graft (65% vs 44%, $p<0.0001$). In a sensitivity analysis defining graft failure as complete occlusion on angiographic follow-up, radial artery graft failure occurred in 16% of grafts compared with 22% of vein grafts and 4% of LIMA grafts (Supplemental Table 1).

Baseline demographic and operative characteristics were similar between recipients of radial artery grafts that experienced graft failure and those with patent radial grafts on follow-up (Supplemental Table 2). Radial graft details stratified by radial graft patency on angiographic follow up are presented in Table 3. The majority of radial artery grafts were used to revascularize the diagonal and obtuse marginal arteries. Target vessels were of similar quality between the two cohorts. Of the 18 failed radial grafts to the left anterior descending, diagonal, left circumflex, obtuse marginal, and right coronary arteries, 13 (72%) were used to bypass lesions with less than 95% stenosis. The radial graft failure rate associated with these target vessels was approximately 37% for lesions less than 75% stenosis, 14% for lesions 75–95% stenosis, and 16% for lesions greater than 95% stenosis.

As shown in Figure 1, there were no statistically significant differences in clinical outcomes between patients who did and did not receive a radial artery graft. Rates of major adverse cardiac events (MACE) were 5.55 per 100 patient-years of follow-up for patients with a radial artery graft compared with 6.88 events per 100 patient-years for patients without a radial artery graft (adjusted HR 0.896; 95% CI 0.609–1.319, $p=0.58$) (Supplemental Figure 2). Individually the rates of death, MI, and repeat revascularization were similar among patients with and without a radial graft.

Discussion

The PREVENT-IV trial included a relatively small proportion of patients that received radial artery grafts. In this post-hoc analysis of PREVENT-IV, we examined rates of graft failure as well as rates of death, MI, and revascularization in patients revascularized with radial artery

grafts compared with all other patients included the angiographic cohort of the trial. We then performed a subgroup analysis of patients revascularized with a radial artery graft; examining differences in characteristics between those with patent or failed radial grafts on 12–18 month angiographic follow up.

In this series, patients who received a radial artery graft had longer index surgeries and longer cardiopulmonary bypass support, possibly a reflection of having more grafts placed. Failure rates of radial artery grafts were comparable to vein grafts and higher than IMA conduits. Patients with radial artery grafts were also more likely to have failure of any graft (radial, IMA, or vein) compared with patients who did not receive a radial artery graft. This too may be the result of having a greater number of grafts placed. While overall graft failure rates were higher in the radial group, there was no difference in patient level outcomes between the two study cohorts including rates of MI, death, need for revascularization, or composite MACE up to 5 years post-operatively. This lack of difference in clinical outcomes was observed despite the radial group being significantly younger. When specifically examining radial graft recipients, while the cohorts were small, there were no obvious differences in baseline demographic or clinical characteristics between those who experienced radial graft failure and those that did not. There was, however, an association with increased radial graft failure rates among grafts used to bypass moderately diseased lesions (<75% stenosis), likely as a result of competitive flow.

In this analysis, we present a radial artery graft failure rate that is higher than much of the previously reported literature. Furthermore, the failure rate of radial grafts presented here is closer to that of vein grafts and farther from IMA grafts than many prior studies. The 2008 RSVP prospective randomized trial by Collins and colleagues, which included 142 patients randomized to use of the radial artery or saphenous vein for revascularization of the native left circumflex, demonstrated improved radial graft patency at five years post-CABG⁸. Similarly, the 2012 RAPS trial by Deb and colleagues, which included 510 patients undergoing CABG with a mean angiographical follow-up time of greater than 7 years also demonstrated improved radial artery patency compared with saphenous vein grafts⁹. The RAPS trial, like PREVENT-IV, demonstrated a trend towards a lower incidence of adverse clinical events associated with radial grafts; however, both were underpowered in their evaluation of clinical outcomes. Unlike these data, a 2011 randomized controlled trial conducted among Veterans Affairs medical centers by Goldman and colleagues, which included 757 participants, did not demonstrate improved graft patency or differences in clinical outcomes associated with radial artery grafting. This study, however, was limited to 1-year angiographic follow up. Similarly, the relatively short angiographic follow up time in this study may have also contributed to the comparable radial artery and vein graft failure rates, as there is some evidence to suggest that radial grafts are associated with lower failure rates more than 4 years post-CABG and venous graft attrition accelerates after this time¹⁵. Furthermore, the higher rates of graft failure seen in PREVENT-IV as compared with other studies may also be the result of varying definitions of graft failure. In this analysis graft failure was defined as >70% stenosis on follow up angiography, however several studies have used an endpoint of complete graft occlusion (Thrombolysis in Myocardial Infarction [TIMI] 0 flow) or >90% stenosis^{7,16,17}. In the present study, a sensitivity analysis of graft failure defined as complete occlusion at angiographic follow-up demonstrated a slightly

lower radial artery graft failure rate. Lastly, the pressure-mediated delivery system used in the PREVENT-IV trial, or other graft handling techniques, may have contributed to the increased rates of graft failure observed ¹³.

Several theories for the mechanism of radial artery graft failure have been proposed. This includes the comparative resistance of arterial grafts to the development of atherosclerosis compared with venous grafts ¹⁸. Also, the relatively thick-walled radial artery compared with the LIMA and RIMA may make it more prone to ischemia as well as vasospasm leading to increased rates of graft stenosis and failure ¹⁹. Usage of the radial artery as a secondary arterial conduit may be preferable to the RIMA at times, however, as there has been an association with bilateral IMA usage and the development of sternal wound complications, especially in diabetic and obese patients ¹⁵. That being said, multiple recent studies including a subanalysis of the Arterial Revascularization Trial by Benedetto and colleagues suggest significantly improved outcomes with the skeletonized IMA approach ²⁰.

Revascularization using the radial artery during CABG has a class I indication in the 2018 ESC/EACTS guidelines for patients with high-grade coronary artery stenosis ²¹. Ultimately, the decision to utilize the radial artery will depend on a number of clinical factors including surgeon experience as well as patient comorbidities. Of note, PREVENT-IV trial investigators received no explicit instruction regarding how they should utilize each particular graft type so the usage patterns in this study are surgeon-derived. Factors such as inadequate saphenous vein conduits or a patient history of chronic kidney disease with a possibility of dialysis dependence may prompt a surgeon to choose to utilize or not utilize the radial artery, respectively. Furthermore, some studies have suggested differential outcomes following radial artery grafting in specific subpopulations including females, diabetics, patients with advanced heart failure, and the elderly, which may help guide clinical decision making ^{22–24}. There are ongoing randomized clinical trials examining the impact of using multiple arterial grafts on clinical and angiographic outcomes as well as the efficacy of external support systems aimed at altering the progression of vein graft stenosis by alleviating stress on the intima and promoting conduit uniformity ^{25,26}. These emerging technologies, in addition to the “no-touch” vein graft harvest technique, could markedly improve saphenous vein graft patency, potentially closer to that of an internal mammary conduit ²⁷.

There are several limitations to this analysis that are worth noting. First, as a post hoc observational analysis of clinical trial data, we are limited by potential residual confounding. A plan for two autogenous vein grafts was required per trial design, which may have influenced the population receiving radial grafts. As a result, radial grafts may have been utilized for fourth or fifth targets of suboptimal quality, influencing radial artery graft patency rates on follow up. That being said, the vein graft failure rate was slightly higher in the radial artery group, suggesting that there are other factors influencing radial graft patency as well. Lastly, while the trial dataset was quite large, only a small number of patients received a radial artery graft, thus limiting the power to detect differences in clinical outcomes.

Conclusion

Radial artery grafts in the PREVENT-IV trial had 1-year graft failure rates comparable to saphenous vein and higher than LIMA grafts. Patients undergoing CABG using a radial artery graft had similar 5-year rates of major adverse cardiac events. Radial graft failure rates were significantly higher when used to bypass moderately diseased lesions, likely as a result of competitive flow. As such, when clinical circumstances permit, the radial artery is an acceptable alternative to utilizing saphenous vein and should be used to bypass severely stenotic target vessels.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. Clinical outcomes.

*Adjusted for patient age, gender, and history of congestive heart failure; IMA internal mammary artery, MACE major adverse cardiac events (composite outcome comprised of MI, death, and revascularization), MI myocardial infarction; Rate calculated as the number of events per 100 patient years of follow-up.

Table 1.

Baseline and operative characteristics of patients stratified by revascularization with a radial artery graft

	Radial Artery Graft (N=117)	No Radial Artery Graft (N=1806)	P-value
Age (years)	56 (51–64)	64 (56–70)	<.001
Female sex	6 (5.1%)	364 (20.2%)	<.001
Caucasian	109 (93.2%)	1632 (90.4%)	0.606
Weight (kg)	91 (84–100)	87 (77–100)	0.006
Comorbidities			
Hypertension	86 (73.5%)	1326 (73.4%)	0.984
Hypercholesterolemia	91 (77.8%)	1373 (76.0%)	0.666
Diabetes	40 (34.2%)	666 (36.9%)	0.559
Current Smoker	27 (23.1%)	396 (21.9%)	0.771
Chronic Lung Disease	9 (7.7%)	264 (14.6%)	0.038
MI	51 (43.6%)	773 (42.8%)	0.867
Within 30 Days	24 (20.5%)	359 (19.9%)	0.868
Prior PCI	30 (25.6%)	494 (27.4%)	0.687
Congestive Heart Failure	3 (2.6%)	143 (7.9%)	0.034
PVD	8 (6.8%)	210 (11.6%)	0.113
CVD	7 (6.0%)	188 (10.4%)	0.124
NYHA class			0.348
I	39 (33.6%)	730 (40.8%)	
II	47 (40.5%)	601 (33.6%)	
III	22 (19.0%)	313 (17.5%)	
IV	8 (6.9%)	147 (8.2%)	
Ejection Fraction	55 (45–60)	50 (40–60)	0.304
Number of Grafts Placed			<0.0001
1	0 (0.0%)	26 (1.4%)	
2	1 (0.9%)	126 (7.0%)	
3	9 (7.7%)	992 (54.9%)	
4+	107 (91.5%)	662 (36.7%)	
Surgery Details			
Type of Surgery			0.984
Emergent/Salvage	3 (2.6%)	51 (2.8%)	
Urgent	56 (47.9%)	852 (47.2%)	
Elective	58 (49.6%)	902 (50.0%)	
Duration of Surgery	253 (218–296)	228 (191–270)	<.001
Duration of Aortic Cross Clamp	60.0 (42.0–80.0)	56.0 (30.0–75.0)	0.072
Cardiopulmonary Bypass	90 (76.9%)	1429 (79.1%)	0.571
Duration of Bypass Pump	110.5 (93.0–137.0)	99.0 (79.0–122.0)	<.001

	Radial Artery Graft (N=117)	No Radial Artery Graft (N=1806)	P-value
ICU Length of Stay (hours)	23 (20–33)	26 (22–47)	0.002
Hospital Length of Stay (days)	6 (5–7)	6 (5–7)	0.858

MI myocardial infarction, PCI percutaneous coronary intervention, PVD peripheral vascular disease, CVD cerebrovascular disease, NYHA New York Heart Association, ICU intensive care unit; N is total number of patients per group

Continuous variables are presented as median (25th – 75th percentile) unless otherwise specified.

Table 2.

Graft- and patient-level failure rates stratified by revascularization with a radial artery graft

Graft Type	Radial Artery Graft (N=452)	No Radial Artery Graft (N=5596)	Total
VG	71/231 (30.7%)	1023/4110 (24.9%)	1094/4341 (25.2%)
LIMA	7/101 (6.9%)	121/1441 (8.4%)	128/1542 (8.3%)
RIMA	3/7 (42.9%)	12/45 (26.7%)	15/52 (28.8%)
Radial	26/113 (23.0%)	-	26/113 (23.0%)
Any Failure (Graft Level)	107/452 (23.7%)	1156/5596 (20.7%)	1263/6048 (20.9%)
Any Failure (Patient Level)	76/117 (65.0%)	801/1806 (44.4%)	877/1923 (45.6%)

IMA internal mammary artery, VG vein graft, LIMA left internal mammary artery, RIMA right internal mammary artery; N is total number of grafts per group

Table 3.

Radial artery graft characteristics among patients who were revascularized with a radial artery graft stratified by graft failure on follow-up

Radial Graft Details	Patent Radial Graft (N=86)	Failed Radial Graft (N=26)
Graft Target		
LAD	6 (6.9%)	1 (3.8%)
D1	18 (20.7%)	1 (3.8%)
LCX	4 (4.6%)	1 (3.8%)
RI	1 (1.1%)	2 (7.7%)
OM1–3	39 (45.3%)	11 (42.3%)
RCA	6 (6.9%)	2 (7.7%)
PDA	3 (3.4%)	2 (7.7%)
D1 to OM1	-	1 (3.8%)
OM1 to OM2	2 (2.3%)	1 (3.8%)
Other	8 (9.2%)	4 (15.4%)
Target Artery Quality		
Good	57 (67.9%)	17 (65.4%)
Fair	22 (26.2%)	6 (23.1%)
Poor	4 (4.8%)	2 (7.7%)
Unknown	1 (1.2%)	1 (3.8%)
Degree of LAD stenosis (grafts to LAD or D1)		
<50%	0/24 (0.0%)	1/2 (50.0%)
50–74%	2/24 (8.3%)	0/2 (0.0%)
75–94%	14/24 (58.3%)	0/2 (0.0%)
95–99%	5/24 (20.8%)	1/2 (50.0%)
100%	3/24 (12.5%)	0/2 (0.0%)
Degree of LCX stenosis (grafts to LCX or OM)		
<50%	2/43 (4.7%)	1/12 (8.3%)
50–74%	7/43 (16.3%)	5/12 (41.7%)
75–94%	21/43 (48.8%)	5/12 (41.7%)
95–99%	9/43 (20.9%)	1/12 (8.3%)
100%	4/43 (9.3%)	0/12 (0.0%)
Degree of RCA stenosis (grafts to RCA or PDA)		
<50%	0/9 (0.0%)	0/4 (0.0%)
50–74%	1/9 (11.1%)	0/4 (0.0%)
75–94%	3/9 (33.3%)	1/4 (25.0%)
95–99%	2/9 (22.2%)	0/4 (0.0%)
100%	3/9 (33.3%)	3/4 (75.0%)

LAD left anterior descending artery, D1 first diagonal artery, LCX left circumflex artery, RI ramus intermedius artery, OM1–3 first to third obtuse marginal artery, RCA right coronary artery, PDA posterior descending artery