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Radial Artery and Saphenous Vein Patency More Than 5 Years After Coronary Artery Bypass Surgery

Results From RAPS (Radial Artery Patency Study)

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Objectives The purpose of this study was to present radial and saphenous vein graft (SVG) occlusion results more than 5 years following coronary artery bypass surgery.

Background In the RAPS (Radial Artery Patency Study) study, complete graft occlusion was less frequent in radial artery compared with SVG 1 year post-operatively while functional occlusion (Thrombolysis In Myocardial Infarction flow grade 0, 1, 2) was similar.

Methods A total of 510 patients <80 years of age undergoing primary isolated nonemergent coronary artery bypass grafting with 3-vessel disease were initially enrolled in 9 Canadian centers. Target vessels for the radial artery and study SVG were the right and circumflex coronary arteries, which had >70% proximal stenosis. Within-patient randomization was performed; the radial artery was randomized to either the right or circumflex territory and the study SVG was used for the other territory. The primary endpoint was functional graft occlusion by invasive angiography at least 5 years following surgery. Complete graft occlusion by invasive angiography or computed tomography angiography was a secondary endpoint.

Results A total of 269 patients underwent late angiography (234 invasive angiography, 35 computed tomography angiography) at a mean of 7.7 ± 1.5 years after surgery. The frequency of functional graft occlusion was lower in radial arteries compared with SVGs (28 of 234 [12.0%] vs. 46 of 234 [19.7%]; p = 0.03 by McNemar's test). The frequency of complete graft occlusion was also significantly lower in radial compared with SVGs (24 of 269 [8.9%] vs. 50 of 269 [18.6%]; p = 0.002).

Conclusions Radial arteries are associated with reduced rates of functional and complete graft occlusion compared with SVGs more than 5 years following surgery. (Multicentre Radial Artery Patency Study: 5 Year Results; NCT00187356) (J Am Coll Cardiol 2012;60:28–35) © 2012 by the American College of Cardiology Foundation

The RAPS (Radial Artery Patency Study) study is a multicentre randomized clinical trial comparing the longitudinal angiographic patency of the radial artery and saphenous vein (1). We previously reported that 1 year after surgery, the primary endpoint of complete graft occlusion was reduced in the radial artery compared with the study saphenous vein graft (SVG) (8.2% vs. 13.6%, p = 0.009) (2). The treatment effect was similar in multivariable models (3). The purpose of this investigation is to report on the patency rates of the radial artery and saphenous vein more than 5 years following surgery. Although complete graft occlusion is the standard endpoint used in SVG occlusion studies, radial grafts with diffuse narrowing or reduced flow would be considered patent by this definition. The primary endpoint for the late study was defined as functional graft occlusion, a more rigorous outcome than complete graft occlusion, which was used for the 1-year comparison.

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Methods

Study population. Details of the study protocol have been previously published (1–3) (Online Appendix). Patients <80 years of age undergoing nonemergent primary isolated coronary bypass surgery with graftable triple-vessel disease and an estimated left ventricular ejection fraction more than 35% were eligible for the study. The target coronary vessels for the study grafts were the circumflex and the right coronary arteries, which had ≥70% diameter narrowing, were ≥1.5 mm in diameter, and were deemed to be of acceptable quality according to visual assessment of the preoperative angiogram by the operating surgeon. The study was approved by the research ethics committee at each participating center. All patients provided written informed consent.

Randomization. Randomization was carried out in the operating room with the use of sealed opaque envelopes stratified by site with a randomly determined block size of 4 to 6. Specifically, within-patient randomization was performed whereby each patient was randomly allocated to undergo surgery according to 1 of 2 strategies; the radial artery was used for the right coronary territory and the study SVG was used for the circumflex region or the radial artery was used for the circumflex territory and the study SVG was used for the right coronary system. An internal thoracic artery (ITA) was used to bypass the left anterior descending artery (LAD) territory. Additional grafts were constructed as necessary with single rather than sequential grafts.

Abbreviations and acronyms

CTA = computed tomography angiography
ITA = internal thoracic artery
LAD = left anterior descending artery
MACE = major adverse cardiac event(s)
SVG = saphenous vein graft

Follow-up angiography. Patients were approached to undergo invasive angiography at least 5 years post-operatively. Computerized tomographic graft angiography using a 64-multislice detector machine (computed tomography angiography [CTA]) was offered to patients who withdrew consent for late invasive angiography. Patients who declined to undergo 1-year angiography were also approached to undergo late angiography. Clini-

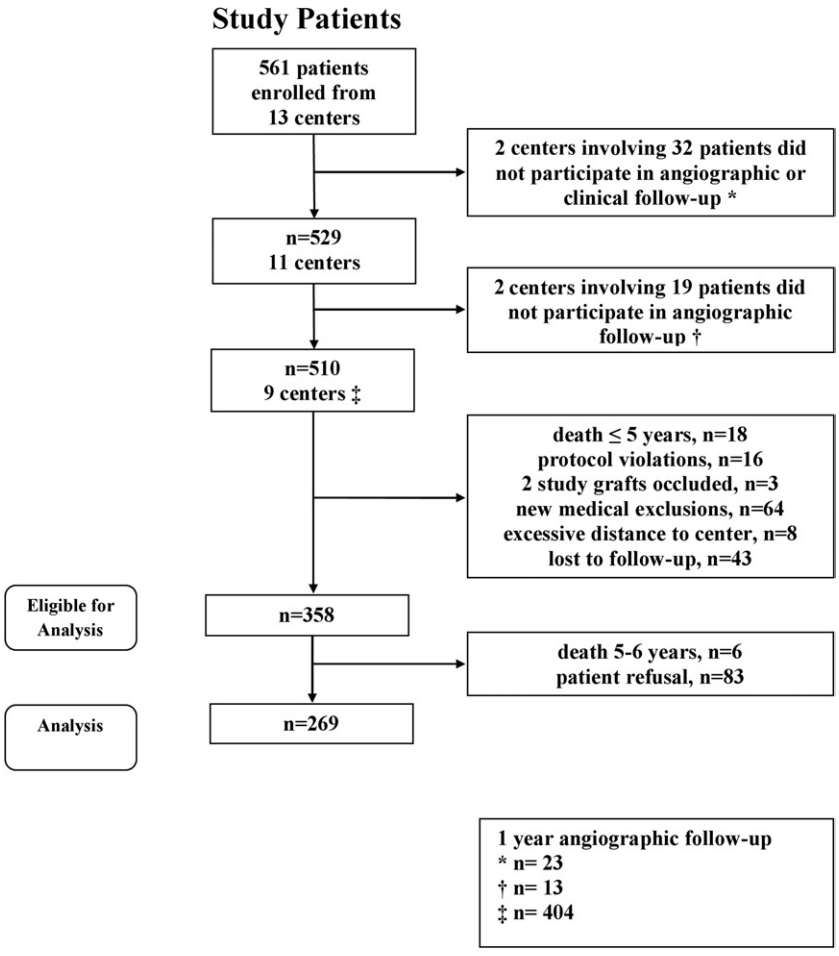

Figure 1 Patient Flow Chart

Flow chart of the 561 patients. Late graft angiography was performed in 269 patients at a mean of 7.7 ± 1.5 years post-operatively.

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cally directed angiograms performed more than 36 months post-operatively also counted toward the primary outcome.

Outcome measures. The primary study endpoint was the proportion of radial artery and study SVG, which were functionally occluded, defined as lack of Thrombolysis In Myocardial Infarction flow grade 3, according to invasive angiography. The secondary angiographic endpoint was the proportion of study grafts that were completely occluded by invasive angiography or CTA.

Follow-up angiograms were reviewed centrally by 5 cardiologists; an imaging cardiologist and a thoracic radiologist read the CT angiograms centrally. Each angiogram was independently adjudicated in a blinded fashion by 2 committee members, with a third review in the case of disagreement of the primary or secondary outcome.

The following late clinical events were recorded: death from any cause, myocardial infarction, repeat coronary surgery, and percutaneous coronary intervention. The com-

Table 1 Baseline Characteristics

Characteristics	All Patients (n = 561, 13 Centers)	Late-Phase Participants (n = 510, 9 Centers)	Late Angiography (n = 269)	No Late Angiography (n = 241)	p Value*
Mean age, yrs	61.0 ± 8.5	60.9 ± 8.3	60.4 ± 8.0	61.4 ± 8.7	0.15
Age ≥70 yrs	111 (19.8)	71 (13.9)	32 (11.9)	39 (16.2)	0.16
Female	75 (13.4)	68 (13.3)	41 (15.2)	27 (11.2)	0.18
Nonelective surgery	196 (34.9)	177 (34.7)	93 (34.6)	84 (34.9)	0.95
Preoperative CCS class					0.63
1	9 (1.6)	9 (1.8)	4 (1.5)	5 (2.1)	
2	133 (23.7)	121 (23.7)	59 (21.9)	62 (25.7)	
3	267 (47.6)	245 (48.0)	137 (50.9)	108 (44.8)	
4	152 (27.1)	135 (26.5)	69 (25.7)	66 (27.4)	
Previous myocardial infarction	264 (47.1)	235 (46.1)	124 (46.1)	111 (46.1)	0.99
History of CHF	18 (3.2)	14 (2.8)	5 (1.9)	9 (3.7)	0.20
Diabetes	148 (26.4)	144 (28.2)	83 (30.9)	61 (25.3)	0.17
Oral hypoglycemics	114 (20.3)	110 (21.6)	67 (24.9)	43 (17.8)	
Insulin	34 (6.1)	34 (6.7)	16 (5.9)	18 (7.5)	
Pre-operative hypertension	271 (48.3)	254 (49.8)	121 (45.0)	133 (55.2)	0.02
Pre-operative dyslipidemia	375 (66.8)	343 (67.3)	189 (70.3)	154 (63.9)	0.11
Current smoker	104 (18.5)	93 (18.2)	43 (16.0)	50 (20.7)	0.16
Pre-operative creatinine, μmol/l	93.0 ± 20.1	93.1 ± 19.2	92.5 ± 17.5	93.8 ± 21.0	0.46
Peripheral vascular disease	50 (8.9)	43 (8.4)	16 (5.9)	27 (11.2)	0.03
Left ventricular grade					0.31
1	272 (48.5)	239 (46.9)	133 (49.4)	106 (44.0)	
2	280 (49.9)	262 (51.3)	131 (48.7)	131 (54.4)	
3	8 (1.4)	8 (1.6)	4 (1.5)	4 (1.6)	
4	1 (0.2)	1 (0.2)	1 (0.4)	0 (0)	
Target vessel stenosis					
>50% stenosis of left main coronary artery	49 (8.7)	49 (9.6)	24 (8.9)	25 (10.4)	0.58
Right coronary artery					0.91
70%–89% stenosis	172 (30.7)	158 (31.0)	84 (31.2)	74 (30.7)	
90%–99% stenosis	161 (28.7)	143 (28.0)	73 (27.1)	70 (29.0)	
100% stenosis	228 (40.6)	209 (41.0)	112 (41.7)	97 (40.3)	
Circumflex artery					0.25
70%–89% stenosis	247 (44.0)	234 (45.9)	115 (42.8)	119 (49.4)	
90%–99% stenosis	200 (35.7)	180 (35.3)	102 (37.9)	78 (32.3)	
100% stenosis	114 (20.3)	96 (18.8)	52 (19.3)	44 (18.3)	
Radial artery target vessel					0.41
70%–89% stenosis	222 (39.6)	205 (40.2)	105 (39.0)	100 (41.5)	
90%–99% stenosis	174 (31.0)	158 (31.0)	82 (30.5)	76 (31.5)	
100% stenosis	165 (29.4)	147 (28.8)	82 (30.5)	65 (27.0)	
Saphenous vein target vessel					0.72
70%–89% stenosis	197 (35.1)	187 (36.7)	94 (34.9)	93 (38.6)	
90%–99% stenosis	187 (33.3)	165 (32.3)	93 (34.6)	72 (29.9)	
100% stenosis	177 (31.6)	158 (31.0)	82 (30.5)	76 (31.5)	

Values are mean ± SD or n (%). *p value compares the difference in the pre-operative demographics between the patients that underwent late angiography (n = 269) and the patients that did not in the 9 centers that participated in late angiographic follow-up.

CCS = Canadian Cardiovascular Society; CHF = congestive heart failure.

posite endpoint of major adverse cardiac events (MACE) was defined as cardiac death, nonfatal myocardial infarction, and any repeat revascularization procedure. Death was considered to be due to cardiac causes unless a definite noncardiac cause was identified. All clinical events were reviewed centrally in a blinded fashion by a committee consisting of 2 cardiologists and 1 cardiac surgeon.

Statistical analysis. The comparison between radial artery and study SVG occlusion was performed on an intention-to-treat basis using the McNemar's test for paired proportional data. An initial test for the treatment (radial artery or SVG) by target vessel interaction was performed with logistic regression. Freedom from late clinical events and cumulative graft patency was summarized using Kaplan-Meier analysis. A p value of 0.05 indicated statistical significance. Statistical analysis was performed with SAS version 9.2 (Cary, North Carolina).

Results

Patient population. Between November 1996 and January 2001, 561 patients were enrolled from 12 university Canadian centers and 1 center from New Zealand, of whom 440 underwent angiography at 1 year post-operatively. Eleven Canadian centers agreed to participate in late clinical follow-up (n = 529); 9 centers participated in the late angiographic study (n = 510) (Fig. 1). There were 358 patients who remained alive and eligible for late angiography 5 years post-operatively. Altogether, 269 of the 358 patients (75%) underwent late angiography at a mean of 7.7 ± 1.5 years after surgery (234 by invasive angiography and 35 by CTA). The last study angiogram was performed in October 2010. Angiography was performed per protocol in 244 patients at 7.8 ± 1.4 years and in 25 patients for clinical reasons at 6.7 ± 1.6 years following surgery. Table 1 lists the baseline patient characteristics (see the Online Appendix for additional details).

Post-operative management. Discharge medications in 529 patients were aspirin in 92%, anticoagulants in 9%, lipid-lowering medications in 49%, beta-blockers in 70%, and angiotensin-converting enzyme inhibitors or angiotensin receptor blockers in 10%. At the time of last follow-up (mean medication follow-up 6.7 ± 3.3 years), 83% were taking aspirin, 9% were taking other antithrombotic medications, 77% were taking a lipid-lowering medication, 56% were taking a beta-blocker, and 51% were taking an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker. Calcium-channel blockers were prescribed in 94% of patients at hospital discharge; 33% of patients continued to take calcium-channel blockers at last follow-up.

Angiographic endpoints. The treatment by target vessel interaction was tested initially for the angiographic endpoints and was nonsignificant by logistic regression. The primary endpoint of functional graft occlusion was reduced in radial arteries compared with SVG (28 of 234 [12.0%] vs. 46 of 234 [19.7%]; p = 0.03 by McNemar's test) (Table 2). Including the 3 patients with occlusion of both radial and SVG at the 1-year study, late radial graft occlusion was 13.1% and SVG occlusion was 20.7%. Functional occlusion of ITA grafts to the LAD was 9.6%. The on-treatment results were identical to the intention-to-treat results. Cumulative graft patency is presented in Figures 2A and 3A.

The frequency of the secondary endpoint of complete graft occlusion was also significantly reduced in the radial artery compared with SVGs (24 of 269 [8.9%] vs. 50 of 269 [18.6%]; p = 0.002) (Table 2). Including the 3 patients with both study grafts occluded at 1 year, radial graft occlusion was 9.9% compared with 19.5% for the SVGs. Corresponding results for ITA grafts to the LAD were 5.9%. Cumulative graft patency is presented in Figures 2B and 3B.

Table 2 Angiographic Endpoints

	Radial Artery	Saphenous Vein	Odds Ratio (95% CI)	Absolute Difference (95% CI)	p Value
TIMI flow grade*					
3	206/234 (88.0)	188/234 (80.3)			
2	2/234 (0.9)	0/234 (0)			
1	5/234 (2.1)	2/234 (0.9)			
0	21/234 (9.0)	44/234 (18.8)	0.45 (0.25–0.80)	9.8% (3.4–16.4%)	0.003
Primary endpoint: functional graft occlusion (TIMI flow grade 0 or 1 or 2)	28/234 (12.0)	46/234 (19.7)	0.58 (0.34–0.97)	7.7% (0.8–14.6%)	0.03
70%–89% proximal stenosis of native vessel disease	15/93 (16.1)†	21/82 (25.6)‡			
≥90% proximal stenosis of native vessel disease	13/141 (9.2)	25/152 (16.4)			
Angiographic string sign*	8/234 (3.4)	0/234 (0)			0.01
Secondary endpoint: complete occlusion§	24/269 (8.9)	50/269 (18.6)	0.46 (0.26–0.77)	9.7% (3.7–15.8%)	0.002
70%–89% proximal stenosis of native vessel disease	12/105 (11.4)‖	22/94 (23.4)¶			
≥90% proximal stenosis of native vessel disease	12/164 (7.3)	28/175 (16.0)			

Values are n/n (%) or odds ratio (95% confidence interval [CI]). The primary and secondary angiographic endpoints of the trial are presented. The reported p values are from McNemar's test results. *Results from invasive x-ray angiography only (n = 234). †For comparison of radial artery grafts with <90% proximal target vessel stenosis with ≥90% proximal target vessel stenosis, p = 0.11, for functional occlusion. ‡For comparison of saphenous vein grafts with <90% proximal target vessel stenosis with ≥90% proximal target vessel stenosis, p = 0.09, for functional occlusion. §Results from invasive X-ray and computed tomography angiography (n = 269). ‖For comparison of radial artery grafts with <90% proximal target vessel stenosis with ≥90% proximal target vessel stenosis, p = 0.25, for complete occlusion. ¶For comparison of saphenous vein grafts with <90% proximal target vessel stenosis with ≥90% proximal target vessel stenosis, p = 0.14, for complete occlusion.

TIMI = Thrombolysis In Myocardial Infarction.

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Clinical endpoints. Table 3 provides the MACE for the 529 study patients. After 1 year, 32 patients had a specific noncardiac cause of death; 21 had a cardiac cause. The overall incidence of MACE was similar in patients who did and did not undergo late angiography (60 of 269 [22.3%] vs. 47 of 260 (18.1%]; p = 0.23). Late survival is presented in Figure 4A and cardiac event–free survival in Figure 4B. Cardiac event–free survival excluding perioperative myocardial infarction was 93.6 ± 1.2% at 7.5 years and 80.4 ± 2.8% at 10 years. Table 4 provides the results for adjudicated cardiac events according to the territory of the graft likely responsible.

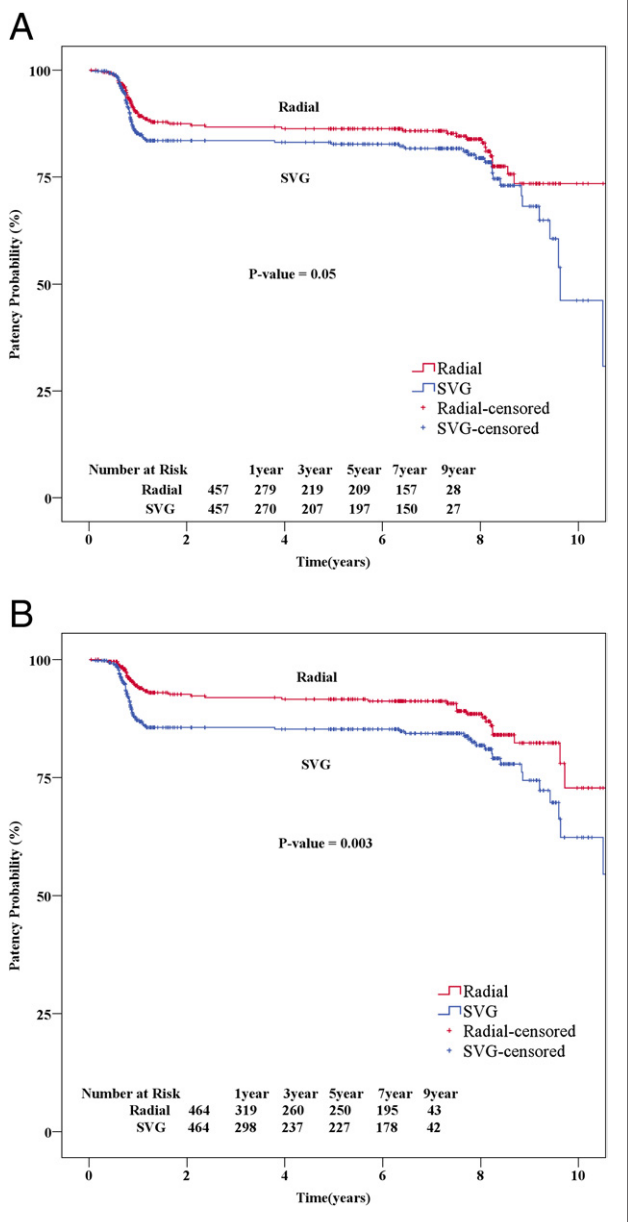

Figure 2 Freedom From Functional and Complete Graft Occlusion

Freedom from **(A)** functional and **(B)** complete radial and saphenous vein graft (SVG) occlusion is presented.

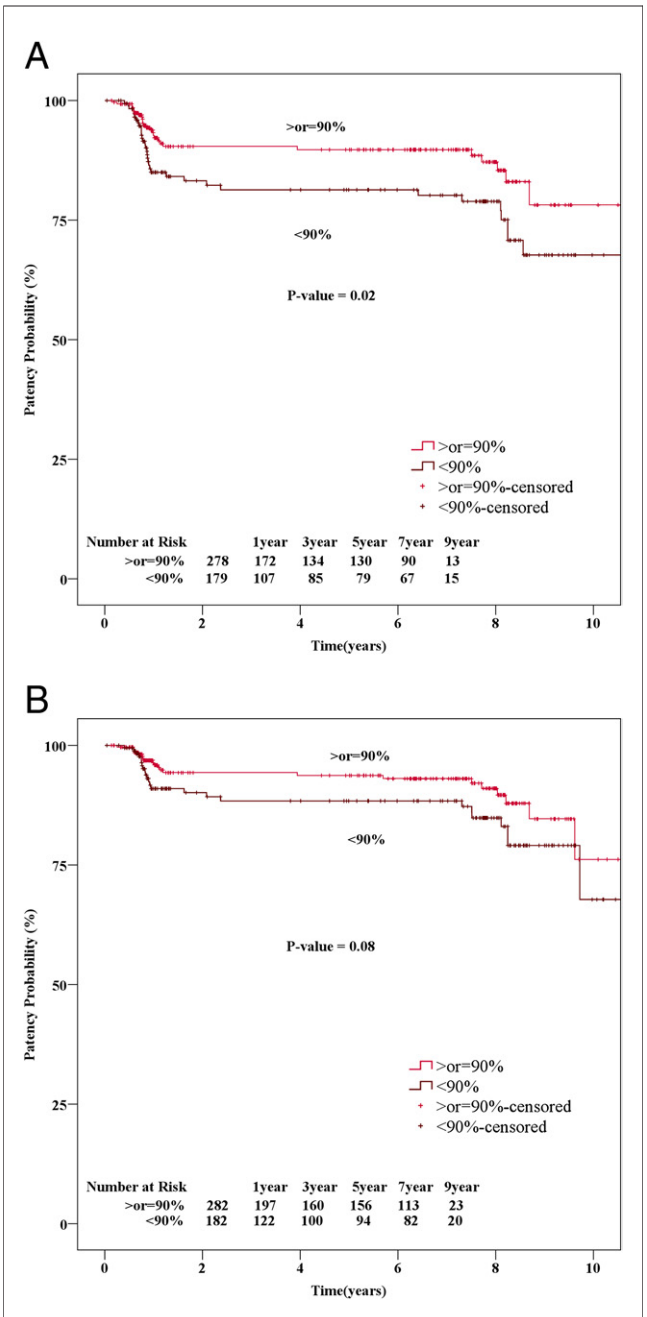

Figure 3 Freedom From Functional and Complete Radial Graft Occlusion According to Target Vessel Stenosis Severity

Freedom from **(A)** functional and **(B)** complete radial graft occlusion is presented according to the severity of the proximal target vessel stenosis.

Discussion

The RAPS study is the first multicenter clinical trial reporting radial graft patency beyond 5 years. In the other and larger multicenter CSP 474 VA trial (4), the radial

Table 3 Major Adverse Cardiac Events (n = 529)

Outcome	≤30 Days	31 Days to 1 Yr	1 Yr to Last Follow-Up	Total Events
Death	3 (0.6)	5 (0.9)	53 (10.0)	61 (11.5)
Death from cardiac causes	1 (0.2)	4 (0.8)	21 (4.0)	26 (4.9)
Nonfatal myocardial infarction	53 (10.0)	1 (0.2)	9 (1.7)	63 (11.9)
Repeat coronary surgery	0	0	2 (0.4)	2 (0.4)
PCI	0	4 (0.8)	24 (4.5)	28 (5.3)
Major adverse cardiac events	54 (10.2)	8 (1.5)	50 (9.5)	107 (20.2)

Values are n (%). The composite endpoint, major adverse cardiac events, is cardiac death, any nonfatal myocardial infarction, repeat coronary surgery, and percutaneous coronary intervention (PCI).

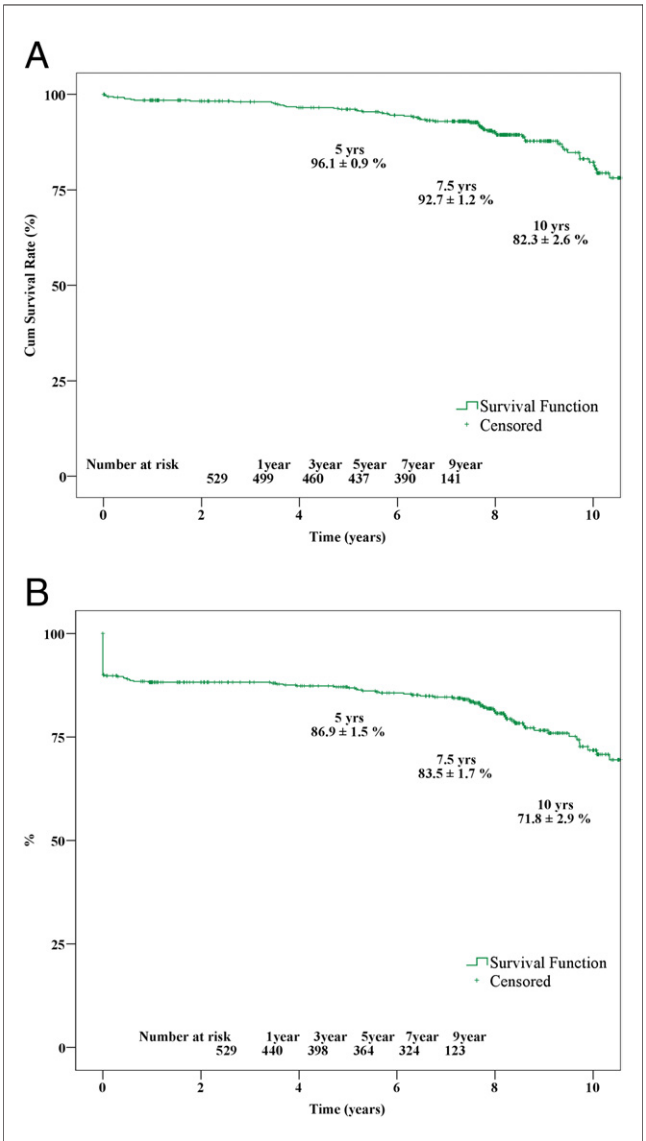

Figure 4 Late Survival and Freedom From MACE

(A) Actuarial survival of the 529 patients is presented. **(B)** Freedom from major adverse cardiac events (MACE) is presented for the 529 patients who had late follow-up. MACE is defined as cardiac death, any myocardial infarction, reoperative coronary surgery, or percutaneous coronary reintervention.

artery or saphenous vein was allocated to the second-best target as determined by the surgeon; they reported that at 1 year, complete graft occlusion was similar in radial and study SVGs (11%)—a 5-year extension is underway. At 5.5 years, the single-center RSVP (Radial Artery Versus Saphenous Vein Patency) study from London, England, reported that complete graft occlusion was markedly less frequent in radial grafts compared with SVGs directed to the circumflex territory (5). There was no apparent graft-by-territory interaction in the RAPS study, indicating that the relative benefit of the radial artery compared with the saphenous vein applies to both the right and circumflex territories. Graft patency was improved when the radial artery was directed to a more severely narrowed target vessel. The single-center Australian RAPCO (Radial Artery Patency and Clinical Outcomes) study scheduled angiographic follow-up within 5 years in a minority of patients and between 5 and 10 years post-operatively in the majority; they have published interim results from 5 to 10 years of follow-up (6).

Athanasiou et al. (7) included both randomized trials and observational studies in a meta-analysis to compare the patency rates across different follow-up intervals—there were 7 studies with a follow-up >5 years. We updated their review with results from the RAPS study and new data complete to April 2011 (6–8). Radial grafting was associated with a reduced rate of late graft occlusion compared with saphenous veins (for observational and randomized trials, odds ratio: 0.520, 95% confidence interval: 0.342 to 0.790, p = 0.002 [Online Fig. 1]; and for randomized trials alone, odds ratio: 0.491, 95% confidence interval: 0.314 to 0.766, p = 0.002 [Online Fig. 2]) (see the Online Appendix for additional details).

Two randomized clinical trials have reported that event-free survival was greater in patients receiving a radial artery (9,10). In the Stand-in-Y trial, event-free survival was similar in patients who received a radial artery compared with a second ITA graft (10). Two moderately large, single-center observational studies using propensity scores have recently been published (11,12). Late survival and event-free survival was enhanced with the use of a radial artery compared with a saphenous vein in 1 (11) but inferior to a second ITA in the other (12).

Table 4 Late Cardiac Outcomes and Study Graft Failure of Adjudicated Cases

Adjudicated Outcomes	Radial Graft Probably or Likely	Study SVG Probably or Likely	Other Graft Probably or Likely	Progression of Native Disease Probably or Likely
Death from cardiac causes (n = 2)	0	1	0	1
Nonfatal myocardial infarction (n = 9)	2	3	3	3
Repeat coronary surgery (n = 2)	0	1	0	1
PCI (n = 22)	3	12	8	5
Patient totals (n = 28)	4	13	8	8

The table shows the results of the adjudicated events. Events were classified using a 5-point scale (very unlikely, unlikely, possibly, probably, or likely) related to either the radial graft, the study saphenous vein graft (SVG), another graft, or progression of native vessel disease. The numbers in the table refer to the number of events and patients that were judged to be "probably or likely" attributed to 1 of the potential causes. A patient could have more than 1 nonfatal event. Overall reviewer agreement was 80% (112 of 140 decisions).

PCI = percutaneous coronary intervention.

Although the design of this trial is powerful for assessing angiographic outcomes, because all patients receive both study grafts, it is weak for the evaluation of clinical outcomes. Akin to coronary stent trials with target lesions or target vessels, we attempted to evaluate whether cardiac events following surgery could be attributed to one or other study graft. Although descriptive and hypothesis generating, our evaluation of adjudicated MACE events showed that there were fewer clinical events assigned to the radial artery than the study saphenous vein.

The incidence of perioperative myocardial infarction in this study was 10%. The incidence of perioperative myocardial infarction seen in the RAPS study is comparable to results from recent multicenter trials of myocardial protection (8.2% in the MEND-CABG II [MC-1 to Eliminate Necrosis and Damage in Coronary Artery Bypass Graft Surgery II] trial, 10.3% in PRIMO-CABG [Pexelizumab for Reduction of Infarction and Mortality in Coronary Artery Bypass Graft Surgery] trial, and 18.6% in the EXPEDITION [Na+/H+ EXchange inhibition to Prevent coronary Events in acute-cardiac conDITIONs] trial) and 9.8% in the PREVENT IV (Project of Ex-vivo Vein Graft Engineering via Transfection IV) trial (13–16). The precise definitions of perioperative myocardial infarction differed in the other studies, but were typically based on marked creatine kinase-myocardial band (CK-MB) elevations, or with new Q waves in association with more modest elevations of CK-MB; in all studies, the CK-MB thresholds were much more conservative than the consensus universal definition (17), suggesting that the incidence of perioperative myocardial infarction was greater than these reported values.

Study limitations. Patients with significant vascular disease and renal insufficiency were excluded, due to the increased risks of protocol-directed research angiography. Radial access coronary angiography was not widely practiced when patients were recruited into the RAPS study. Patients were screened with a pre-operative duplex scan of the forearm. Despite pre-operative screening, the size, length, or quality of the radial conduit was the primary reason for 5 of the protocol violations and 1 of the crossovers.

Patients recruited into the RAPS study were generally of low risk. Late angiography was not performed in 23% of patients who remained eligible (although MACE was only 15.7% in these patients), an additional 13% were excluded for various medical conditions, and 8% were lost to follow-up. The patients who underwent angiography had a lower prevalence of hypertension and peripheral vascular disease compared with patients who did not undergo angiography. Furthermore, although the overall incidence of MACE was similar in the patients who did and did not undergo late angiography, nonfatal outcomes were more frequent in patients who underwent late angiography while fatal events occurred more frequently in the patients who did not. Ascertainment bias may exist (see the Online Appendix for additional details).

Lipid-lowering medications were prescribed in 49% of patients at discharge and 77% at last follow-up; increased utilization may have preferentially improved SVG patency. Separate McNemar's tests were performed; improvement in radial patency compared with saphenous veins was observed in patients on and off statins at last follow-up (see the Online Appendix for additional details).

Conclusions

The RAPS study supports the use of the radial artery as a second arterial conduit, or as a third arterial conduit in association with both ITA grafts, particularly for patients with high-grade target vessel proximal stenoses. The benefit of the radial artery compared with a vein graft persists over 7.5 years.

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Key Words: graft patency ■ radial artery ■ RCT ■ saphenous vein.

APPENDIX

For an expanded Methods section and supplemental figures, please see the online version of this article.