Off-Pump Coronary Artery Bypass Surgery Is Associated With Worse Arterial and Saphenous Vein Graft Patency and Less Effective Revascularization

Results From the Veterans Affairs Randomized On/Off Bypass (ROOBY) Trial

Brack Hattler, MD; John C. Messenger, MD; A. Laurie Shroyer, PhD; Joseph F. Collins, ScD; Scott J. Haugen, MD; Joel A. Garcia, MD; Janet H. Baltz, RN; Joseph C. Cleveland, Jr, MD; Dimitri Novitzky, MD, PhD; Frederick L. Grover, MD; for the Veterans Affairs Randomized On/Off Bypass (ROOBY) Study Group

Background—The Department of Veterans Affairs Randomized On/Off Bypass (ROOBY) trial compared clinical and angiographic outcomes in off-pump versus on-pump coronary artery bypass graft (CABG) surgery to ascertain the relative efficacy of the 2 techniques.

Methods and Results—From February 2002 to May 2007, the ROOBY trial randomized 2203 patients to off-pump versus on-pump CABG. Follow-up angiography was obtained in 685 off-pump (62%) and 685 on-pump (62%) patients. Angiograms were analyzed (blinded to treatment) for FitzGibbon classification (A = widely patent, B = flow limited, O = occluded) and effective revascularization. Effective revascularization was defined as follows: All 3 major coronary territories with significant disease were revascularized by a FitzGibbon A-quality graft to the major diseased artery, and there were no new postanastomotic lesions. Off-pump CABG resulted in lower FitzGibbon A patency rates than on-pump CABG for arterial conduits (85.8% versus 91.4%; \( P = 0.003 \)) and saphenous vein grafts (72.7% versus 80.4%; \( P < 0.001 \)). Fewer off-pump patients were effectively revascularized (50.1% versus 63.9% on-pump; \( P < 0.001 \)). Within each major coronary territory, effective revascularization was worse off pump than on pump (all \( P \leq 0.001 \)). The 1-year adverse cardiac event rate was 16.4% in patients with ineffective revascularization versus 5.9% in patients with effective revascularization (\( P < 0.001 \)).

Conclusions—Off-pump CABG resulted in significantly lower FitzGibbon A patency for arterial and saphenous vein graft conduits and less effective revascularization than on-pump CABG. At 1 year, patients with less effective revascularization had higher adverse event rates.

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Key Words: coronary artery bypass ■ coronary artery bypass, off-pump

Several relatively small single-center and multicenter randomized studies and large, risk-adjusted observational studies have reported that off-pump coronary artery bypass graft surgery (CABG) results in less morbidity than on-pump CABG.\(^1\)\(^-\)\(^8\) In these studies and others, concerns have been raised about graft patency and long-term outcomes with the off-pump approach.\(^9\)\(^1\)\(^0\) To assess the relative efficacy of off-pump versus on-pump CABG, the Department of Veterans Affairs (VA) Cooperative Studies Program funded the Randomized On/Off Bypass (ROOBY) Trial, the largest prospective randomized study completed to date comparing these 2 surgical approaches. The 2 primary hypotheses of the ROOBY trial were that 30-day and 1-year outcomes would be no different between the 2 surgical techniques. The ROOBY trial confirmed that 30-day adverse composite outcome and short-term morbidities were similar between the 2 arms. However, 1-year adverse composite outcome consisting of all-cause death, nonfatal myocardial infarction (MI), and...
repeat revascularization from the time of surgery to 1 year was 47% higher with off-pump CABG (14.6% versus 9.9%; \( P<0.001 \)).11

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The major secondary hypothesis of the ROOBY trial was that 1-year graft patency rates would be no different for off-pump versus on-pump CABG regardless of coronary territory, target artery, and/or type of conduit. Furthermore, it was hypothesized that at 1 year the quality of revascularization would be similar between treatments. Overall, the ROOBY trial found that the graft patency rate was lower with off-pump than on-pump CABG (82.6% versus 87.8%, respectively; \( P<0.001 \)).11 This ROOBY trial angiographic core laboratory report provides detailed comparative outcomes of graft patency and quality of revascularization between the 2 surgical treatment arms.

**Methods**

The ROOBY trial was a controlled, single-blinded, randomized trial conducted from February 2002 through May 2008 at 18 VA Medical Centers (VAMCs). The trial was approved by the Institutional Review Board at each VAMC and by the VA Cooperative Studies Program Human Rights Committee. All patients provided written informed consent. Patients were randomized with a blocked randomization scheme balanced within center and by attending surgeon. Surgeons were required to have at least 20 cases experience in the off-pump technique before participating in the study. The average pre-study case experience was 120 cases (median, 50). Further details of the study design, enrollment, and inclusion/exclusion criteria have previously been published.11 Before subject randomization, every pre-study case experience was 120 cases (median, 50). Further details of the study design, enrollment, and inclusion/exclusion criteria have previously been published.11

Baseline, interim, and 1-year angiograms for every patient were baseline, interval, and 1-year angiograms for every patient were reviewed independently by 2 cardiologists blinded to treatment assignment. When there was a difference in opinion on patency and/or effective revascularization, the films were reviewed and a consensus was reached by use of the opinion of a third cardiologist when necessary. The angiographic core laboratory was located at the Denver VAMC. Angiograms on CD-ROM were downloaded to a central image server and were evaluated with commercially available quantitative coronary angiography analysis software (Camtronics Medical Systems). Angiograms on cine film or CD that were not compatible with core laboratory software were evaluated with Fowler handheld electronic digital calipers (Sylvac) that were accurate to the nearest 0.01 mm. The coronary arteries were subdivided into segments as done in the Bypass Angioplasty Revascularization Investigation (BARI) trial, which has been endorsed by the American College of Cardiology/American Heart Association coronary angiography guidelines.11,13,14 Vessel size was determined in the least foreshortened view with end-diastolic frames. Percent stenosis was calculated by comparing the narrowest diameter of a lesion in any view with the most normal proximal or distal reference segment in the same frame. An artery or graft with \( \geq 50\% \) diameter narrowing of a segment with a reference diameter \( \geq 1.5 \) mm was considered to have a clinically significant stenosis. Vessel diameter was reported to the nearest 0.1 mm. Left anterior descending (LAD) territory grafts were those anastomosed to the LAD or diagonal branches. Circumflex territory grafts were defined as grafts to the ramus intermedius and obtuse marginals. Right coronary artery (RCA) territory grafts were those to the inferior and posterior walls and included grafts to the RCA, posterior descending artery, or posterolaterals in right-dominant systems and to the left posterior descending artery and left posterolaterals in left-dominant systems.

At baseline, the mean severe lesion in each coronary artery segment and the diameter of the vessel distal to the lesion were recorded. At follow-up angiography, grafts were evaluated by use of the usual definition of patency (open versus closed) and were assessed for FitzGibbon patency with the A, B, and O classification system in which FitzGibbon A is an excellent/unimpaired graft, B is an impaired graft with a stenosis \( >50\% \) reducing the caliber of the graft to \( <50\% \) of the target artery diameter, and O is a completely occluded graft. Grafts with a string sign with minimal flow were classified as FitzGibbon B.15,16 In a few cases, patency (open versus closed) could be determined but the FitzGibbon classification could not be assigned because of poor angiographic visualization. These poorly opacified but open grafts were classified as FitzGibbon O to denote an unknown FitzGibbon class.

The 3 major coronary regions (LAD, left circumflex, and RCA) were also evaluated for the quality of revascularization using prespecified criteria. Each coronary region was scored as effectively revascularized when a FitzGibbon A graft supplied the major diseased artery within the territory, the graft was appropriately placed distal to the primary stenosis, and there was no new coronary lesion just distal to the anastomosis of the graft. A new lesion just distal to the graft anastomosis was considered to likely be a result of surgical technique such as the use of snares. However, de novo lesions downstream from the grafts (eg, in the distal LAD beyond a mid-LAD anastomosis) were not scored as ineffective revascularization. In cases when 1 coronary region was supplied by 2 grafts, if the major or largest diseased artery (eg, the LAD artery within the LAD region) was supplied by a FitzGibbon A graft as described above, then that coronary territory was considered effectively revascularized. For example, if the LAD artery was supplied by a FitzGibbon A graft but another graft to a diagonal branch was occluded, the LAD territory was still scored as effectively revascularized. If a bypass graft to the major diseased artery within a territory was FitzGibbon B but there was a new significant lesion just distal to the anastomosis, then that territory was scored as ineffectively revascularized. At follow-up angiography, a patient was considered to have overall effective revascularization if all of the major coronary regions (LAD, circumflex, and/or RCA) with disease were effectively revascularized.

Before participating in the study, all ROOBY angiographic core laboratory cardiologists underwent a training and validation process. Through the use of a prespecified test set of 30 angiograms from patients with previous CABG, intraobserver and interobserver validation was performed to ensure consistent assessment of graft patency, FitzGibbon classification, and effective revascularization. On a follow-up set of 30 angiograms, interrater reliability for graft patency (open versus closed graft), FitzGibbon classification, and effective revascularization was excellent with \( >98\% \) agreement.

Most of the baseline characteristics and end points for patients who had angiographic follow-up in ROOBY were discrete variables. Fisher exact tests were used to compare treatment groups for variables having 2 possible responses (eg, yes versus no), including graft patency, the effectiveness of revascularization at angiographic follow-up, and the major adverse end point. The used \( t \) tests for variables having \( \geq 2 \) possible responses such as FitzGibbon classification analysis, ejection fraction, and number of vessels with coronary disease. Age, number of grafts planned per patient, and number of grafts completed per patient were compared by use of \( \chi^2 \) tests. Because these analyses were planned originally as part of the secondary hypotheses of the ROOBY trial, a value of \( P<0.01 \) (using 2-sided tests) was pre-established to represent statistical significance. All outcomes were analyzed by intention to treat. Data collection and statistical analysis were performed by the VA Cooperative Studies Program Coordinating Center at Perry Point, MD.
Results

Enrollment/Randomization

The ROOBY trial randomized 2203 veterans to either on-pump (n=1099) or off-pump (n=1104) CABG (the Figure). Overall, 1370 of the study group (62.2%) had follow-up angiography at an average of 368 days after surgery in both treatment groups. The majority (n=1334) had angiography performed at the 12-month end-of-study visit, whereas 36 subjects had only interim, clinically driven angiography. The mean time to clinically driven angiography after CABG in these 20 on-pump and 16 off-pump patients was 184.2 and 222.1 days, respectively (P=0.46). The primary reasons that patients had no follow-up catheterization were patient refusal (n=628), death (n=70), elevated serum creatinine (n=52), or loss to follow-up (n=47). Among patients who had follow-up angiography, the 1-year composite end point was analyzed in all but 5 subjects who were lost to follow-up.

Patients who underwent follow-up angiography were healthier than those who did not. ROOBY study subjects without follow-up angiography (n=833) were older (average age, 64.0 versus 62.0 years; P<0.001), more often diabetic (47.2% versus 41.5%; P<0.01), and more frequently had a history of prior MI (33.6% versus 28.1%; P<0.01).

In the study subjects with follow-up angiography, there were no significant differences in baseline demographic and clinical characteristics between treatment arms (Table 1). Consistent with the overall veteran population receiving CABG, the vast majority of subjects were male (99%). About one third of patients were current smokers. Most patients had 3-vessel coronary artery disease (66%) and normal left ventricular function (61%). Approximately one fourth of patients had left main disease (≥50% stenosis). Only 4 patients had a previous CABG surgery. The most frequent comorbidities were hypertension (84%), diabetes mellitus (42%), prior MI (28%), chronic obstructive pulmonary disease (20%), and peripheral vascular disease (14%).

The average number of grafts planned per patient was 3.0±0.9 in both arms, but the average number of grafts completed per patient was significantly less in the off-pump arm (2.9±0.9 off pump versus 3.1±1.0 on pump; P<0.01). There were no significant differences between arms in the types of conduits used, with 96% of patients receiving internal mammary artery grafts (97% of which were to the LAD), 93% saphenous vein grafts (SVGs), and 8% radial arteries. The rate of endovascular harvesting of saphenous vein conduit was balanced at ~38% in each treatment group. Medical therapy was excellent with >95% rates of aspirin, lipid-lowering medication, and β-blocker use at 1 year in both treatment arms. At 1 year, 18% of patients in each arm continued to smoke cigarettes.

Graft Patency

In the 1370 patients with follow-up angiography, 4092 grafts were completed and evaluated by the angiographic core laboratory. As previously reported, overall graft patency (open versus closed) was worse with the off-pump technique.11 As shown in Table 2, overall FitzGibbon A patency was also worse with off-pump CABG (77.5% versus 84.4%; P<0.001). Compared with on-pump patients, more FitzGibbon B or flow-limited grafts were found in the off-pump arm (n=86 [4.3%] versus n=57 [2.7%]). Of these FitzGibbon B grafts, an anastomotic lesion was the cause of flow limitation in 31.4% of off-pump versus 24.6% of on-pump cases.
Overall, 29 of the 4092 grafts (0.7%) were classified as FitzGibbon U because they were open but were not sufficiently visualized to determine FitzGibbon class A or B. The worse overall FitzGibbon graft patency rate with the off-pump technique was due largely to lower FitzGibbon class A patency in SVG conduits (72.7% versus 80.4% on pump; P < 0.001). Arterial graft patency was excellent in both arms (92.9% off pump versus 94.8% on pump; P = 0.13). However, FitzGibbon A patency for arterial grafts was 85.8% with off-pump CABG, which was significantly lower than the 91.4% rate with on-pump CABG (P < 0.003). Of the arterial grafts, most were left internal mammary artery (LIMA) pedicles. There were only 112 radial artery grafts (51 off pump and 61 on pump), and the patency of radials was similar (P = 0.38). Overall, 29 of the 4092 grafts (0.7%) were classified as FitzGibbon U because they were open but were not sufficiently visualized to determine FitzGibbon class A or B. The worse overall FitzGibbon graft patency rate with the off-pump technique was due largely to lower FitzGibbon class A patency in SVG conduits (72.7% versus 80.4% on pump; P < 0.001). Arterial graft patency was excellent in both arms (92.9% off pump versus 94.8% on pump; P = 0.13). However, FitzGibbon A patency for arterial grafts was 85.8% with off-pump CABG, which was significantly lower than the 91.4% rate with on-pump CABG (P < 0.003). Of the arterial grafts, most were left internal mammary artery (LIMA) pedicles. There were only 112 radial artery grafts (51 off pump and 61 on pump), and the patency of radials was similar.
between treatments (84.3% off pump versus 83.6% on pump; \(P=1.0\)).

Graft patency details by coronary territory, by target artery, and by conduit to each target artery are presented in Table 3. Grafts (n=1876) to the LAD artery and diagonal branches were considered LAD territory grafts. The patency rate of all grafts to the LAD territory was marginally lower off pump than on pump (88.9% versus 91.9%; \(P=0.03\)). However, FitzGibbon A patency of all grafts to the LAD territory was significantly worse off pump compared with on pump (83.2% versus 89.3%; \(P<0.001\)). As previously reported, the quality of LIMA pedicle grafts to the LAD artery was significantly worse off pump; FitzGibbon A patency was 89.0% off pump versus 93.2% on pump (\(P=0.01\)). Graft patency to the diagonals was 76.7% off pump and 82.2% on pump (\(P=0.14\)), a nonsignificant trend resulting from the lower number of diagonal branch arteries bypassed in each treatment arm.

Overall graft patency and FitzGibbon A patency rates to the circumflex and RCA systems were significantly worse off pump compared with on pump (85.0% versus 89.3%; \(P=0.01\)). The vast majority of grafts to the circumflex and RCA systems were SVGs (90.8% and 96.8%, respectively), and differences in SVG patency between treatment arms appeared to be the major factor in the lower off-pump patency rate for every coronary region. Very few right internal mammary artery pedicle, free right internal mammary artery, or free LIMA conduits were used in the ROOBY study (64 overall). The patency rate of radial artery grafts to the circumflex system was nearly equal at \(83\%\) in both arms. There were no coronary regions, no coronary artery target vessels, and no types of conduit used in which the graft patency rates significantly favored off-pump CABG.

### Table 3. Graft Patency and FitzGibbon A Classification by Major Coronary Region, Target Artery, and/or Conduit

<table>
<thead>
<tr>
<th></th>
<th>Off Pump, n/N (%)</th>
<th>On Pump, n/N (%)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patency of all grafts to LAD territory</td>
<td>831/935 (88.9)</td>
<td>865/941 (91.9)</td>
<td>0.03</td>
</tr>
<tr>
<td>FitzGibbon A to LAD territory</td>
<td>778/935 (83.2)</td>
<td>840/941 (89.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patency of all grafts to circumflex territory</td>
<td>434/554 (78.3)</td>
<td>523/616 (84.9)</td>
<td>0.004</td>
</tr>
<tr>
<td>FitzGibbon A to circumflex territory</td>
<td>411/554 (74.2)</td>
<td>498/616 (80.8)</td>
<td>0.008</td>
</tr>
<tr>
<td>Patency of all grafts to RCA territory</td>
<td>385/509 (75.6)</td>
<td>450/537 (83.8)</td>
<td>0.001</td>
</tr>
<tr>
<td>FitzGibbon A to RCA territory</td>
<td>360/509 (70.7)</td>
<td>429/537 (79.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patency of all grafts to LAD artery</td>
<td>627/669 (93.7)</td>
<td>639/666 (95.9)</td>
<td>0.08</td>
</tr>
<tr>
<td>FitzGibbon A to LAD artery</td>
<td>586/669 (87.6)</td>
<td>618/666 (92.8)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Patency of LIMA pedicles to LAD artery</td>
<td>589/618 (95.3)</td>
<td>611/635 (96.2)</td>
<td>0.48</td>
</tr>
<tr>
<td>FitzGibbon A LIMA pedicles to LAD artery</td>
<td>550/618 (89.0)</td>
<td>592/635 (93.2)</td>
<td>0.01</td>
</tr>
<tr>
<td>Patency of SVGs to LAD artery</td>
<td>25/33 (75.8)</td>
<td>45/54 (83.3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Patency of all grafts to diagonals</td>
<td>204/266 (76.7)</td>
<td>226/275 (82.2)</td>
<td>0.14</td>
</tr>
<tr>
<td>FitzGibbon A to diagonals</td>
<td>192/266 (72.2)</td>
<td>222/275 (80.7)</td>
<td>0.03</td>
</tr>
<tr>
<td>Patency by conduit to diagonals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SVG</td>
<td>172/229 (75.1)</td>
<td>196/244 (80.3)</td>
<td>0.18</td>
</tr>
<tr>
<td>LIMA pedicle</td>
<td>23/26 (88.5)</td>
<td>28/28 (100.0)</td>
<td>0.10</td>
</tr>
<tr>
<td>Patency by conduit to circumflex territory*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SVG</td>
<td>400/512 (78.1)</td>
<td>470/550 (85.5)</td>
<td>0.002</td>
</tr>
<tr>
<td>Radial</td>
<td>24/29 (82.8)</td>
<td>45/54 (83.3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Patency of all grafts to RCA</td>
<td>97/122 (79.5)</td>
<td>91/105 (86.7)</td>
<td>0.16</td>
</tr>
<tr>
<td>FitzGibbon A to RCA</td>
<td>88/122 (72.1)</td>
<td>89/105 (84.8)</td>
<td>0.04</td>
</tr>
<tr>
<td>Patency of all grafts to PDA/PL branches</td>
<td>280/378 (74.1)</td>
<td>346/418 (82.8)</td>
<td>0.003</td>
</tr>
<tr>
<td>FitzGibbon A to PDA/PL branches</td>
<td>264/378 (69.8)</td>
<td>328/418 (78.5)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

LAD indicates left anterior descending artery; RCA, right coronary artery; SVG, saphenous vein graft; LIMA, left internal mammary artery; PDA, posterior descending artery; and PL, posterolateral.

*Circumflex territory grafts were those to the obtuse marginals and ramus intermedialis.

Adverse Cardiac End Points in the Angiographic Group

Consistent with the overall cohort of the ROOBY trial, within the angiographic group, adverse cardiac events tended to occur more frequently after off-pump CABG. The 1-year nonfatal MI rate, which included perioperative MI, was 8.1% off pump versus 5.6% on pump (\(P=0.09\)). Repeat revascularization rates were 6.3% off pump and 3.7% on pump (\(P=0.03\)).

Effectiveness of Revascularization

On-pump patients more frequently had all grafts patent than off-pump patients (71.2% versus 63.5%; \(P<0.01\)) at 12
months. Because graft patency does not always translate into an excellent revascularization outcome, the angiographic core laboratory assessed each coronary territory for whether the territory was effectively revascularized. This effective revascularization evaluation included assessments of whether a graft was patent, whether the graft had a significant lesion, whether the graft was placed proximal or distal to the existing primary coronary stenosis, whether new lesions had developed just distal to the anastomosis, and whether significant native disease in a targeted vessel was actually bypassed. The ROOBY angiographic core laboratory found that all 3 major coronary territories were effectively revascularized with the off-pump technique (Table 4). In addition to lower graft patency and fewer grafts completed than planned in the off-pump arm, another major cause of less effective revascularization in off-pump CABG was a new lesion in the native coronary artery at or just distal to the graft anastomosis. This occurred in 4.3% of off-pump grafts compared with 2.2% of on-pump grafts (P<0.001). Overall, only 50.1% of off-pump and 63.9% of on-pump patients (P<0.001) had an effective revascularization to all diseased territories.

To assess whether ineffective revascularization was associated with worse outcomes, 1-year nonfatal MI and repeat revascularization rates were compared between patients with all coronary territories effectively revascularized and patients with 1 or more ineffectively revascularized territories. The 1-year nonfatal MI and repeat revascularization rates were significantly higher in subjects who were incompletely revascularized (Table 5). The relative risk of an adverse composite event was 2.77 (95% confidence interval, 1.98–3.87; P<0.001) times higher in patients with 1 or more ineffectively revascularized coronary regions. The highest 1-year composite adverse event rate (19.7%) was seen in patients with ineffective revascularization of the LAD territory. One-year outcomes were also assessed by use of the following index of completeness of revascularization: The number of grafts completed was greater than or equal to the number of grafts planned.17 Patients completely revascularized by this definition had a trend toward a lower 1-year composite adverse end-point rate than patients with fewer grafts completed than planned (9.9% versus 13.5%, respectively; P=0.13).

### Discussion

The ROOBY trial represents the largest randomized controlled study of off-pump versus on-pump CABG to date. This report from the ROOBY angiographic core laboratory provides details on graft patency and the quality of revascularization to address the major secondary hypothesis of the trial. As seen in the overall ROOBY trial cohort, in this angiographic subset of patients, the 30-day composite adverse outcome rate was no different between arms, but the off-pump group had more adverse cardiovascular outcomes at 1 year.1

The major finding from the angiographic core laboratory was that graft patency was consistently and significantly worse with off-pump CABG. This was true for all 3 major coronary regions, including grafts to the LAD territory. As seen in smaller randomized trials using very experienced off-pump surgeons, LIMA-to-LAD patency was excellent and nearly equal between treatment arms (95% in each). This patency rate was similar to prior reports by Widimsky et al.,10 who reported arterial graft patency of 91% for both techniques, and Puskas et al.,4 who reported arterial patency rates to the LAD of 97.2% off pump and 98.7% on pump. However, in the ROOBY study, there were significantly fewer widely patent (FitzGibbon A) LIMA pedicle grafts off-pump than on-pump CABG (89.0% versus 93.2%; P=0.01). This is an important finding because other studies have reported patency based on open versus occluded grafts but have not reported the quality of LIMA grafts by distinguishing between FitzGibbon A and B patency classification.4,6,10

In the ROOBY study, the 1-year patency rate of arterial grafts (n=1489) was 92.9% off pump versus 94.8% on pump (P=0.13). In the Puskas et al4,17 reports on graft patency from the Surgical Management of Arterial Revascularization Therapies (SMART) trial, 1-year arterial graft patency was 94.1% off pump compared with 98.1% on pump, an absolute difference that was actually greater than the absolute difference between treatments in ROOBY. Although the number of open or patent arterial grafts was similar between treatments

### Table 4. Quality of Revascularization at Angiographic Follow-Up*

<table>
<thead>
<tr>
<th>Off Pump, n/N (%)</th>
<th>On Pump, n/N (%)</th>
<th>Relative Risk† (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient with all grafts patent</td>
<td>435/685 (63.5)</td>
<td>488/685 (71.2)</td>
<td>0.89 (0.83–0.96)</td>
</tr>
<tr>
<td>LAD territory effectively revascularized‡</td>
<td>580/665 (87.2)</td>
<td>623/672 (92.7)</td>
<td>0.94 (0.91–0.98)</td>
</tr>
<tr>
<td>Circumflex territory effectively revascularized‡</td>
<td>355/525 (67.6)</td>
<td>417/538 (77.5)</td>
<td>0.87 (0.81–0.94)</td>
</tr>
<tr>
<td>RCA territory effectively revascularized‡</td>
<td>329/516 (63.8)</td>
<td>390/522 (74.7)</td>
<td>0.85 (0.79–0.93)</td>
</tr>
<tr>
<td>Patient effectively revascularized§</td>
<td>343/685 (50.1)</td>
<td>438/685 (63.9)</td>
<td>0.78 (0.71–0.86)</td>
</tr>
</tbody>
</table>

CI indicates confidence interval; LAD, left anterior descending artery; and RCA, right coronary artery.

†Relative risk estimates compare off-pump and on-pump CABG. A relative risk <1.0 indicates less likelihood of achieving effective revascularization with off-pump technique.

‡A territory was considered effectively revascularized when its major diseased artery was revascularized by a FitzGibbon A graft, the graft anastomosis was distal to the major stenosis, and there was no new lesion just distal to the anastomosis.

§A patient was considered effectively revascularized when all of the 3 major coronary regions with disease were effectively revascularized.
in ROOBY, FitzGibbon A patency of arterial grafts was significantly worse off pump (85.8%) than on pump (91.4%; \( P = 0.003 \)). A direct comparison of the quality of arterial patency in the ROOBY trial and other studies is difficult because most other studies have reported only the combined FitzGibbon A and B patency rates or the open graft rate, failing to make the important distinction between the widely patent FitzGibbon A graft and the flow-limited, stenotic FitzGibbon B graft.\(^{4,6,9,10,18,19}\)

The absolute difference in SVG patency between arms was 7.2% better with on-pump CABG (\( P < 0.001 \)). This absolute difference is comparable to those in other trials that have reported absolute differences ranging from 4.0% to 10.0%, all favoring on-pump CABG.\(^{6,9,10,18,19}\) The 1-year patency rates for arterial and SVG conduits in ROOBY compare favorably with other reports, supporting the quality and expertise of the participating surgeons.\(^{16,20,21}\)

Complete revascularization is always the ideal goal of a CABG procedure. In the ROOBY trial, patients in the off-pump arm were more likely to have fewer grafts completed than were planned, were more likely to have an occluded or impaired graft, and were more likely to have a new lesion just distal to the graft anastomosis. These problems with revascularization were among a combination of factors that led to nearly 50% of off-pump patients having incomplete revascularization compared with 35.6% of on-pump patients (\( P < 0.0001 \)). Significant clinical implications may be derived from these findings. For example, the repeat revascularization rate of 6.3% in the off-pump treatment arm was 1.7 times higher than the 3.7% rate in the on-pump arm (\( P = 0.03 \)). A higher repeat revascularization rate after off-pump CABG has also been found in other large nonrandomized trials.\(^{22,23}\) As noted in a recent editorial, surgeons continue to fear incomplete revascularization with off-pump CABG, and anastomotic performance may be the Achilles heel of off-pump surgery.\(^{24}\)

Incomplete or ineffective revascularization was associated with worse cardiovascular outcomes at 1 year. Patients who had 1 or more poorly revascularized territories or ineffective LAD territory revascularization had high 1-year adverse event rates that were significantly worse than for subjects who were effectively revascularized. Interestingly, there was no significant difference in the 1-year composite adverse outcome rate between patients who had fewer grafts completed than were planned compared with patients who had as many as or more grafts completed than planned.

Several weaknesses may limit the findings and generalizability of the study. Overall, 64.3% of the 1-year survivors of the ROOBY trial underwent follow-up catheterization. This follow-up angiography rate is comparable to those in 3 other smaller off-pump versus on-pump trials and a larger VA aspirin study in which 1-year follow-up angiography rates ranged from 63.6% to 76.5%.\(^{4,10,20,25}\) Selection bias was evident in that veterans who underwent follow-up angiography were younger and healthier than those who did not. Despite this, the patients in the angiographic subset still had comorbidity and 3-vessel coronary artery disease rates that were comparable to or higher than the rates seen in other off-pump trials.\(^{2,4,6,9,18}\)

The number of statistical tests used to analyze the secondary hypotheses raises the potential for a multiple comparisons challenge. Accordingly, for these secondary outcomes, a
more stringent value of $P=0.01$ was used to denote statistical significance to reduce the likelihood of potentially spurious statistical findings. Finally, 99.4% of the original ROOBY trial enrollees were male; hence, the findings may not be applicable to women.

**Conclusions**

In the ROOBY trial, graft patency and effective revascularization at 1 year were significantly better with conventional on-pump CABG. Graft patency was better with on-pump CABG for all 3 major coronary regions and for both arterial and vein conduits. Patients with effective revascularization were less likely to have had a nonfatal MI or repeat revascularization by 1 year after CABG. Thus, differences in graft quality and patency between the 2 arms may explain the differences seen in the 1-year adverse composite outcome favoring on-pump CABG. Further long-term follow-up of the ROOBY trial patients appears warranted to determine whether the adverse outcome differences between the 2 arms diverge further or abate over time.

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**Disclosures**

None.

**References**


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**CLINICAL PERSPECTIVE**

The Department of Veterans Affairs Randomized On/Off Bypass (ROOBY) trial is the largest trial to date to compare angiographic outcomes in off-pump versus on-pump coronary artery bypass graft (CABG) surgery. One-year follow-up angiography was obtained in 685 off-pump and 685 on-pump patients. Angiograms were analyzed in a blinded manner by intention to treat. Grafts were classified as patent (open versus closed) and were assessed for quality with the FitzGibbon classification system. Every patient was also assessed for effective revascularization, which was defined as follows: All 3 major coronary territories with significant disease were revascularized by a FitzGibbon A-quality graft to the major diseased artery, the graft was placed in proper position relative to native disease, and there were no new postanastomotic lesions. Effective revascularization has not been reported previously in a study of post-CABG graft patency. This study is the first randomized study of off-pump versus on-pump CABG to indicate that both graft patency and effective revascularization are clearly worse with off-pump CABG. FitzGibbon graft patency was worse for arterial, left internal mammary artery pedicle, and vein graft conduits. In addition, every coronary territory was revascularized less effectively with off-pump CABG. At the 1-year follow-up angiography, \( \approx 50\% \) of off-pump CABG patients had at least 1 coronary territory that was at risk for ischemia. Those patients with less effective revascularization had significantly more adverse cardiac events by 1 year after CABG.

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Off-Pump Coronary Artery Bypass Surgery Is Associated With Worse Arterial and Saphenous Vein Graft Patency and Less Effective Revascularization: Results From the Veterans Affairs Randomized On/Off Bypass (ROOBY) Trial

Brack Hattler, John C. Messenger, A. Laurie Shroyer, Joseph F. Collins, Scott J. Haugen, Joel A. Garcia, Janet H. Baltz, Joseph C. Cleveland, Jr, Dimitri Novitzky and Frederick L. Grover for the Veterans Affairs Randomized On/Off Bypass (ROOBY) Study Group

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