A Randomized Comparison of the Transradial and Transfemoral Approaches for Coronary Artery Bypass Graft Angiography and Intervention

The RADIAL-CABG Trial (RADIAL Versus Femoral Access for Coronary Artery Bypass Graft Angiography and Intervention)

Tesfaldet T. Michael, MD, MPH, Mohammed Alomar, MD, Aristotelis Papayannis, MD, Owen Mogabgab, MD, Vishal G. Patel, MD, Bavana V. Rangan, BDS, MPH, Michael Luna, MD, Jeffrey L. Hastings, MD, Jerrold Grodin, MD, Shuaib Abdullah, MD, Subhash Banerjee, MD, Emmanouil S. Brilakis, MD, PhD

Dallas, Texas

Objectives This study sought to compare and contrast use and radiation exposure using radial versus femoral access during cardiac catheterization of patients who had previously undergone coronary artery bypass graft (CABG) surgery.

Background Limited information is available on the relative merits of radial compared with femoral access for cardiac catheterization in patients who had previously undergone CABG surgery.

Methods Consecutive patients (N = 128) having previously undergone CABG surgery and referred for cardiac catheterization were randomized to radial or femoral access. The primary study endpoint was contrast volume. Secondary endpoints included fluoroscopy time, procedure time, patient and operator radiation exposure, vascular complications, and major adverse cardiac events. Analyses were by intention-to-treat.

Results Compared with femoral access, diagnostic coronary angiography via radial access was associated with a higher mean contrast volume (142 ± 39 ml vs. 171 ± 72 ml, p < 0.01), longer procedure time (21.9 ± 6.8 min vs. 34.2 ± 14.7 min, p < 0.01), greater patient air kerma (kinetic energy released per unit mass) radiation exposure (1.08 ± 0.54 Gy vs. 1.29 ± 0.67 Gy, p = 0.06), and higher operator radiation dose (first operator: 1.3 ± 1.0 mrem vs. 2.6 ± 1.7 mrem, p < 0.01; second operator 0.8 ± 1.1 mrem vs. 1.8 ± 2.1 mrem, p = 0.01). Fewer patients underwent ad hoc percutaneous coronary intervention (PCI) in the radial group (37.5% vs. 46.9%, p = 0.28) and radial PCI procedures were less complex. The incidences of the primary and secondary endpoints was similar with femoral and radial access among PCI patients. Access crossover was higher in the radial group (17.2% vs. 0.0%, p < 0.01) and vascular access site complications were similar in both groups (3.1%).

Conclusions In patients who had previously undergone CABG surgery, transradial diagnostic coronary angiography was associated with greater contrast use, longer procedure time, and greater access crossover and operator radiation exposure compared with transfemoral angiography. (RADIAL Versus Femoral Access for Coronary Artery Bypass Graft Angiography and Intervention [RADIAL-CABG] Trial; NCT01446263). (J Am Coll Cardiol Intv 2013;6:1138–44) © 2013 by the American College of Cardiology Foundation

From the VA North Texas Healthcare System and University of Texas Southwestern Medical Center, Dallas, Texas. Dr. Michael has received a cardiovascular training grant from the National Institutes of Health, Award Number T32HL007360. Dr. Banerjee is on the Speakers’ Bureau of St. Jude Medical, Medtronic Corp., and Johnson & Johnson; is a consultant for Medtronic and Covidien; and has
Several studies have demonstrated that compared with transfemoral (TF) access cardiac catheterization and percutaneous coronary intervention (PCI), using transradial (TR) access is associated with lower rates of vascular and bleeding complications (1–4), reduced mortality (5–7), earlier ambulation (8), and improved patient satisfaction (9). However, there are limited data on the role of TR catheterization in patients who previously underwent coronary artery bypass graft (CABG) surgery (10–13), who were often excluded or underrepresented in TR access studies (4,7,14,15). Although observational studies have suggested that TR PCI in patients who had previously undergone CABG surgery is feasible and safe (10–13), it is technically more challenging than procedures performed via TF access.

We conducted the RADIAL–CABG (RADIAL Versus Femoral Access for Coronary Artery Bypass Graft Angiography and Intervention) trial to compare contrast volume, radiation exposure, and procedural clinical outcomes of diagnostic coronary angiography and PCI among patients who had previously undergone CABG surgery and were randomized to TR versus TF access.

**Methods**

**Study design and patient population.** The RADIAL–CABG trial was a single-center, prospective, randomized, controlled clinical trial designed to compare procedural variables and outcomes of TR versus TF catheterization in patients who had previously undergone CABG surgery and were referred for clinically indicated coronary angiography and PCI. Between October 2011 and March 2013, all patients who had previously undergone CABG surgery and were referred for diagnostic or interventional cardiac catheterization at our institution were screened for participation. Patients presenting with ST-segment elevation acute myocardial infarction, abnormal Allen test results, known difficulty obtaining vascular access via either the femoral or radial artery, or age >90 years were excluded. The study was approved by the Dallas VA Medical Center institutional review board, and all patients provided written informed consent before cardiac catheterization. Patients were randomized to TR or TF access in a 1:1 ratio using opaque, numbered, sealed envelopes containing randomization assignment based on a computer-generated random sequence.

**Procedure description.** TF catheterization was performed via the right or left common femoral artery, as clinically indicated. Hemostasis was achieved using manual compression or a vascular closure device, at the operator’s discretion. TR catheterization was performed via the left radial artery in all patients to facilitate cannulation of the left internal mammary artery graft. In most cases, the operator was standing on the right side of the patient. Intravenous heparin (70 U/kg) and intra-arterial nitroglycerin (200 μg) were administered via the radial sheath to prevent arterial spasm and thrombosis. At the end of each TR procedure, a TR band (Terumo, Somerset, New Jersey) was applied for 15 to 60 min to achieve patent hemostasis.

**Operators.** Each procedure was performed by 2 operators. The first operator was usually a cardiology trainee and the second operator an interventional cardiologist with TR expertise (>1,000 procedures performed). If the first operator failed to obtain arterial access after 2 or 3 attempts, the second operator obtained arterial access. Similarly, if the first operator failed to engage the target coronary arteries or bypass grafts within 2 to 3 min, the second operator performed the native coronary artery and bypass graft cannulation.

**Endpoints.** The primary study endpoint was the volume of radiographic contrast administered during cardiac catheterization. Secondary endpoints included fluoroscopy time, total procedure time (defined as the interval between administration of local anesthesia for obtaining vascular access and removal of the last catheter), radiation exposure of the patient and operators, vascular access crossover, vascular access complications, and peri-procedural major adverse cardiac events (MACE). All endpoints were assessed separately for diagnostic angiography and for PCI (i.e., measurements for diagnostic catheterization ended with completion of diagnostic angiography and measurements for PCI began on PCI initiation and ended on PCI completion). MACE were defined as all-cause death, Q-wave myocardial infarction, recurrent angina requiring urgent repeat target vessel revascularization with PCI or coronary bypass surgery, and stroke occurring before hospital discharge. Vascular complications included hematoma, aneurysm, pseudoaneurysm, arteriovenous fistula formation, retroperi-toneal hematoma, dissection, and limb ischemia. Major bleeding was defined as a hemoglobin decrease of at least 3 g/dl or administration of a blood transfusion.

**Data collection.** Demographic and clinical characteristics of patients as well as detailed procedural characteristics were
prospectively collected. For patients undergoing ad hoc PCI in addition to diagnostic angiography, the various study endpoints were recorded separately for diagnostic angiography and for PCI. The data on performance of aortography (to determine bypass graft anatomy), arterial access crossover, and periprocedural complications were collected. The patients’ cumulative skin dose was calculated from air kerma values. The operators’ radiation exposure was measured using a pocket dosimeter device (BleeperSv, Vertec, Berkshire, United Kingdom). Data regarding patient satisfaction including access site and overall discomfort, earliest time to ambulation after the procedure, and future access site preference were collected the day after the procedure.

**Statistical analysis.** Categorical variables were presented as percentages and compared using the chi-square or Fisher’s exact test, as appropriate. Continuous variables were presented as mean ± SD and compared using the t test or Wilcoxon rank sum test, as appropriate. Assuming a mean contrast volume of 165 ± 65 ml in patients who had previously undergone CABG surgery undergoing TF cardiac catheterization (16), a sample size of 128 patients was needed to have 80% power to detect 20% higher contrast use with TR access (alpha = 0.05).

All statistical analyses were performed with JMP version 9.0 (SAS Institute Inc., Cary, North Carolina). Analyses were performed by intention-to-treat, and a p value of <0.05 was considered statistically significant.

**Results**

During the study period, 237 patients were screened for participation. Of these, 109 patients were excluded (Fig. 1), leaving a total of 128 patients for enrollment and randomization (64 to TR access and 64 to TF access). Nearly all (126 of 128) study patients underwent diagnostic angiography, whereas 2 patients only underwent PCI. The mean patient age was 65.7 ± 8.2 years; all patients were men, and most presented with stable angina. The baseline characteristics of the 2 study groups were well balanced (Table 1).

**Procedural outcomes for diagnostic coronary angiography.**

Angiographic and procedural data for diagnostic coronary angiography (n = 126) are depicted in Table 2. Compared with TF access, patients undergoing cardiac catheterization via TR access had higher contrast use (142 ± 39 ml vs. 171 ± 72 ml, p < 0.01), longer procedure duration...
The arterial access crossover rates were 17.2% for TR and 0% for TF (p = 0.01). The reasons for failure were radial artery dissection (n = 1), radial artery perforation (n = 1), and inability to engage a native coronary artery (n = 1) or a saphenous vein graft (n = 8). Aortography was performed in 6.2% of the patients in both groups. An arterial closure device was used in 54.7% of the patients in the TF group as follows: Angio-Seal (St. Jude Medical, St. Paul, Minnesota) in 26 patients (74.3%); Perclose (Abbott Vascular, Santa Clara, California) in 6 patients (17.1%); and EXOSEAL (Cordis, Miami Lakes, Florida) in 3 patients (8.6%).

**Procedural outcomes of PCI.** In the PCI cohort, more patients underwent ad hoc PCI in the TF group (n = 30) than those in the TR group (n = 24) (p = 0.28) (Table 3). In 4 patients who were randomized to TR access, ad hoc PCI was not performed due to anticipated procedural complexity; PCI was performed the following day in 3 patients and 2 days later on the fourth patient using TF access. Stent use and saphenous vein graft interventions were significantly more common in the TF access group. No significant differences were observed in contrast volume, procedure time, fluoroscopy time, and patient/operator radiation exposure (Table 3).

**Clinical outcomes.** All PCI attempts were successful in both groups, and there were no major perioperative complications. One patient in the TF group had transient numbness of the right upper extremity that lasted <30 min and

### Table 1. Demographic and Baseline Characteristics of the Study Population

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Radial Access</th>
<th>Femoral Access</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>64.7 ± 6.3</td>
<td>66.7 ± 6.3</td>
<td>0.15</td>
</tr>
<tr>
<td>Men, %</td>
<td>100.0</td>
<td>100.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>31.9 ± 5.5</td>
<td>30.0 ± 5.4</td>
<td>0.22</td>
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<tr>
<td>Clinical presentation</td>
<td></td>
<td>4.7 min vs. 12.7 min</td>
<td>0.01</td>
</tr>
<tr>
<td>Stable angina</td>
<td>35.9</td>
<td>46.8</td>
<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>20.3</td>
<td>18.7</td>
<td></td>
</tr>
<tr>
<td>NSTEMI</td>
<td>10.9</td>
<td>12.5</td>
<td></td>
</tr>
<tr>
<td>Other*</td>
<td>32.8</td>
<td>21.9</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>92.2</td>
<td>92.2</td>
<td>1.00</td>
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<td>Hyperlipidemia</td>
<td>94.0</td>
<td>98.4</td>
<td>0.55</td>
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<td>Diabetes</td>
<td>50.0</td>
<td>60.9</td>
<td>0.21</td>
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<td>Current smoking</td>
<td>14.1</td>
<td>15.6</td>
<td>0.80</td>
</tr>
<tr>
<td>Previous smoking</td>
<td>89.6</td>
<td>90.6</td>
<td>0.77</td>
</tr>
<tr>
<td>Heart failure</td>
<td>43.6</td>
<td>56.3</td>
<td>0.21</td>
</tr>
<tr>
<td>No. of years since CABG surgery</td>
<td>7.7</td>
<td>9.5</td>
<td>0.16</td>
</tr>
<tr>
<td>No. of patients</td>
<td>53.3</td>
<td>46.7</td>
<td>0.48</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>51.4</td>
<td>48.6</td>
<td>0.72</td>
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<tr>
<td>Previous stroke</td>
<td>9.3</td>
<td>4.7</td>
<td>0.29</td>
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<tr>
<td>Peripheral artery disease</td>
<td>14.1</td>
<td>9.38</td>
<td>0.41</td>
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<tr>
<td>Known CABG anatomy</td>
<td>82.8</td>
<td>90.6</td>
<td>0.19</td>
</tr>
</tbody>
</table>

**Values given are mean ± SD or %. ** Ventricular arrhythmias, cardiomyopathy, study follow-up. CABG = coronary artery bypass graft; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention.

### Table 2. Procedural Outcomes and Resource Use in Percutaneous Diagnostic Coronary Angiography

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Radial Access</th>
<th>Femoral Access</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrast volume, ml</td>
<td>171 ± 72</td>
<td>142 ± 39</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Procedure time, min</td>
<td>34.2 ± 14.7</td>
<td>21.9 ± 6.8</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Fluoroscopy time, min</td>
<td>12.7 ± 6.6</td>
<td>8.5 ± 4.7</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Patient air kerma radiation exposure, Gy</td>
<td>1.29 ± 0.67</td>
<td>1.08 ± 0.54</td>
<td>0.06</td>
</tr>
<tr>
<td>First operator radiation exposure, mrem</td>
<td>2.6 ± 1.7</td>
<td>1.3 ± 1.0</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Second operator radiation exposure, mrem</td>
<td>1.8 ± 2.1</td>
<td>0.8 ± 1.1</td>
<td>0.01</td>
</tr>
<tr>
<td>No. of patient grafts</td>
<td>2.2 ± 1.0</td>
<td>2.3 ± 0.9</td>
<td>0.56</td>
</tr>
<tr>
<td>No. of diagnostic catheters used</td>
<td>3.3 ± 1.3</td>
<td>2.9 ± 0.7</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**Values are mean ± SD.**
spontaneously subsided. Magnetic resonance imaging of the brain did not demonstrate any acute injury. A total of 4 patients (2 from each group) had minor vascular complications (3.1% each). In the TR group, 1 patient had radial artery intimal dissection and another patient had minor radial artery perforation. Both patients had a patent left radial artery on discharge. In the TF group, groin hematomas developed in 2 patients with no evidence of aneurysm, pseudoaneurysm, arteriovenous fistula formation, or significant decrease in hemoglobin.

All patients completed a questionnaire before hospital discharge. The preferred access for future cardiac catheterization was TR in 48%, followed by either access in 26% and TF in 26%. When analyzed according to randomization, patients in the TR group were likely to prefer radial access compared with patients in the TF group, as depicted in Figure 2 (p < 0.01).

Discussion

The major findings of the RADIAL-CABG trial are that among patients who previously had undergone CABG surgery and now require diagnostic angiography, compared with TF access, TR access was associated with: 1) greater contrast use; 2) longer procedure and fluoroscopy time; 3) greater patient and operator radiation exposure; 4) higher crossover rates to TF; and 5) greater patient satisfaction. No significant differences in these parameters were observed among patients undergoing PCI, although PCI via TF access appeared to be more complex than PCI via TR access.

The RADIAL-CABG trial is the first prospective, randomized, controlled trial to compare procedural efficiency and outcomes with TR access versus TF access among patients who had previously undergone CABG surgery and scheduled to undergo diagnostic angiography and/or PCI. Diagnostic angiography via TR access was associated with greater contrast and catheter use and operator radiation exposure. This is not surprising because engaging bypass grafts via TR access can be more challenging than via TF access, especially via the left radial approach. The greater difficulty in engaging a bypass graft was also reflected in the high access crossover rates (17.2% with TR vs. 0% with TF). Although the first operator in many cases was a cardiology trainee, an experienced interventional cardiologist promptly assumed the primary operator role if difficulty was encountered, including all crossover cases. Such a “fellow first” strategy may have contributed to higher failure and crossover rates because multiple access attempts and excessive catheter manipulation can lead to radial artery spasm and/or intimal dissection. Our TR to TF access crossover rate of 17% is higher than the 3.8% to 5.8% rates reported in retrospective studies on patients who had previously undergone CABG surgery by other authors (10–12). Several factors might have contributed to this difference, such as the “fellow-first” strategy, selection bias in observational studies, and possibly differences in the patient populations included in various studies. However, in a large academic center, the overall crossover rate from TR to TF access was 9.1% during transition from TF to TR as the preferred vascular access (65% of all procedures were done using TR access during the study period) (17).

When attempting cardiac catheterization using TR access, TF crossover may be needed because of inability to puncture or cannulate the radial artery (10,15,18–22), radial artery spasm (15,20–22), failure to advance catheters or guidewires (10,15,18,22), and inability to cannulate/engage the target vessel (11,15,23). In cases of TR access failure,
prompt crossover to TF access may shorten the total procedure time (24), but there is no universally accepted threshold for performing the switch; hence, it is heavily dependent on each operator’s experience and judgment. Published literature on TR versus TF access often reports no significant difference in procedure times, contrast use, or radiation exposure between the 2 approaches; however, most of these studies were not randomized trials, making the results subject to selection bias. Furthermore, even among randomized trials that included patients who had previously undergone CABG surgery, those patients only formed a small minority of the total study cohort (8–13,15,23,25–31). The finding of a prolonged procedure time with TR access is in agreement with the findings of Brueck et al. (15) and Sallam et al. (27), but this was not observed in other studies (9–12,14). Some of the possible reasons for this discrepancy could be underrepresentation of CABG patients in the majority of these studies, selection bias, and the learning curve of fellows who often assumed the role of a primary operator.

Consistent with multiple previous studies, fluoroscopy time was significantly longer with TR access (1,4,25,26,28,31), likely reflecting the increased technical difficulty of cannulating native coronary arteries and bypass grafts using this approach. As a result, TR access was associated with a numerically higher but nonsignificant trend (p = 0.055) toward higher air kerma patient radiation exposure, which is similar to findings of previous studies (13,25,26,28,29,31). From an operator perspective, TR access was associated with significantly greater operator radiation exposure during diagnostic angiography compared with TF access. Although this may be at least partially explained increased fluoroscopy time required to engage bypass grafts from a TR approach, another likely contributing factor is use of the left radial access, which often requires the operator to “bend over” the patient and, hence, be more exposed to radiation. Increased operator radiation exposure with TR access is described in multiple previous studies (23,26,28) and is a cause for concern because over time it can lead to significant adverse health consequences.

No difference was observed in procedural efficiency and radiation exposure between TF access and TR access during PCI; however, this is likely explained by differential case selection. TF access PCI was of higher complexity compared with TR access, as suggested by the greater number of stents and longer total stent length. Four patients in the TR group did not undergo ad hoc PCI, but instead returned for PCI via TF access within the first 2 days after diagnostic angiography. In contrast, all TF access patients requiring PCI underwent ad hoc PCI. A major advantage of the TR versus the TF approach is the lower rate of major vascular access complications; however, no such difference was observed in the present study, likely due to small sample size and an overall low incidence of MACE. Moreover, the exclusion of patients with ST-segment elevation myocardial infarction from the study and higher crossover rate (along with intention-to-treat analysis) might have contributed to the absence of the favorable MACE and vascular access complication outcomes that have been reported in the TR access group in previous studies. Consistent with previous reports (9,32), patient satisfaction was greater with TR access.

Our study raises several questions about the relative risks and benefits associated with TR access versus TF access in patients who had previously undergone CABG surgery. Whether the longer procedure duration and greater resource use and radiation exposure (to patient and operator) with TR access are sufficiently offset by improved patient comfort and the lower likelihood of vascular access complications needs to be assessed for each individual patient. This decision is complicated by that fact that almost 1 in 5 patients who had previously undergone CABG surgery may require crossover from a TR to TF approach when undergoing cardiac catheterization.

Study limitations. First, as expected in a predominantly male veteran population, only men were included in the study, which may limit extrapolation to women. Men often have several comorbidities (33) and challenging coronary anatomy; however, most patients who had previously undergone CABG surgery undergoing coronary angiography and PCI are men (34). Second, the decision to perform ad hoc PCI in the 2 study groups was at the discretion of the operator, and as a result, fewer TR access patients underwent ad hoc PCI. Third, cardiology trainees who have less experience in using TR access often served as first operators, which may result in increased contrast and fluoroscopy use; however, an experienced operator was overseeing every procedure and promptly assumed the primary operator role when needed. Fourth, the high crossover rates from TR to TF access may have attenuated the differences between the 2 study groups, although differences were still highly statistically significant for most endpoints.

Conclusions

In summary, TR access for diagnostic angiography in patients who had previously undergone CABG surgery was associated with lower procedural efficiency and higher contrast and radiation exposure for both the patient and the operator, but also greater patient satisfaction. This information can assist with access site selection in this challenging group of patients.

Reprint requests and correspondence: Dr. Emmanouil S. Brilakis, Dallas VA Medical Center (111A), 4500 South Lancaster Road, Dallas, Texas 75216. E-mail: esbrilakis@gmail.com.
REFERENCES


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