multicenter, randomized clinical trial of 561 patients that compared both kinds of grafts.

One-year outcomes from RAPS were published in 2004 [Desai ND et al. *N Engl J Med* 2004]. The primary hypothesis was that radial artery grafts would be superior to SVG at 1 year and again at 5 years of follow-up. Patients who were undergoing nonemergency CABG with graftable triple-vessel disease and an estimated ejection fraction >35% were enrolled and received a left internal mammary artery bypass graft to the left anterior descending artery, one radial artery graft, and one SVG. The location of the radial artery graft (right coronary vs left circumflex) was selected at random, with the other artery receiving a SVG. In this type of randomization scheme, variance is minimized, since randomization is performed *within* rather than *between* patients, with each patient serving as his or her own control. The primary endpoint at 1 year was the proportion of total graft occlusion, and perfect graft patency (TIMI flow grade 3) was a secondary endpoint. Other secondary endpoints included proximal and distal anastomotic stenosis and stenosis in the body of the graft. Patients were excluded if they had renal insufficiency or the inability to utilize both potential conduits (ie, patients with varicose veins or vein stripping, nonpalpable ulnar arteries or positive Allen's test on clinical exam, abnormal upper extremity Doppler ultrasonography, vasculitis, or Reynaud's syndrome). The primary statistical analysis was performed on an intention-to-treat basis, with a p value of <0.048 considered to indicate significant superiority, considering a single interim analysis.

Postoperative angiography was performed at 1 year in 440 of the 561 enrolled patients; complete graft occlusion was higher in SVGs than in radial artery grafts (13.6% vs 8.2%; p=0.009), a relative risk reduction of 40%. Diffuse narrowing of the graft was more frequent in radial artery grafts than SVGs (7.0% vs 0.9%; p=0.001). In patients with patent grafts, angiographic stenosis at the proximal anastomosis was higher with radial artery grafts than with SVGs (21.4% vs 11.1%, p<0.001). Radial artery grafts had less stenosis in the graft body (5.7% vs 12.3%; p=0.003), with no significant difference at the distal anastomosis. Perfect graft patency (ie, TIMI grade flow 3) was similar for both grafts (87.7% for radial vs 85.7% for saphenous). Clinical endpoints could not be compared between graft strategies, considering that randomization was *within* rather than *between* patients; however, overall mortality was 1.4% at 1 year, and perioperative myocardial infarction was similar (~3%) between the radial and SVG regions.

Five-year angiographic follow-up was available in 269 patients. In this subgroup, the mean age was 60 years, 15% was female, one-third of procedures were for an urgent indication, and one-third was diabetic. In this 5-year follow-up analysis (mean interval from surgery 7.6 ± 1.5 years), the authors swapped the original primary endpoint of proportion of total graft occlusion for functional graft occlusion (TIMI flow grade 0–2). Nevertheless, this subgroup still demonstrated an association with less total graft occlusion (TIMI grade flow 0) in the radial artery versus SVG group (8.9% vs 17.8%; OR, 0.50; 95% CI, 0.32 to 0.80; p=0.004). Functional graft occlusion was also lower for radial artery grafts compared with SVGs (12.0% vs 18.8%; OR, 0.64; 95% CI, 0.41 to 0.98; p=0.05). In grafts with TIMI 3 flow, proximal and distal anastomotic stenosis was similar for both grafts, but stenosis in the body of the graft was more common with SVGs (15.2% vs 6.7%; p=0.02). This translated into a reduction in complete occlusion or stenosis in the radial grafts (33.8% vs 21.9%; OR, 0.58; 95% CI, 0.40 to 0.86; p=0.004).

Overall, among patients who were undergoing elective CABG, the RAPS study demonstrated that radial arteries are associated with an approximate 9% sustained benefit from graft occlusion and less graft disease than saphenous veins at 5 years. This translates into a "number needed to treat" with radial bypass (in place of SVG) of ~12 patients to prevent 1 additional graft occlusion.

Radial Access is Not Superior to Femoral Access for Coronary Angiography or Intervention in Patients with ACS

A large, randomized multicenter trial has shown that radial access for coronary angiography with possible percutaneous coronary intervention (PCI) is not superior to femoral access. In secondary and exploratory analyses, the study observed that radial access was associated with a reduction in major vascular access site complications, was superior for the primary outcome when performed at high-volume radial centers, and was associated with better outcomes for patients with ST-segment elevation myocardial infarction (STEMI). Sanjit S. Jolly, MD, McMaster University, Hamilton, Ontario, Canada, presented the findings of the study.

The Radial versus Femoral Access for Coronary Intervention (RIVAL; NCT01014273) trial was designed to provide randomized controlled trial data to test the hypothesis that radial access is superior to femoral access in patients with acute coronary syndrome (ACS) who are undergoing PCI. This hypothesis was generated by

a meta-analysis that showed a significant reduction in bleeding events with radial access, with a trend toward fewer ischemic events, among patients with ACS [Jolly SS. *Am Heart J* 2009].

The RIVAL trial first enrolled patients as part of the ACS trial CURRENT-OASIS 7 [CURRENT–OASIS 7 Investigators. *N Engl J Med* 2010]. Patients were included in RIVAL if an invasive approach was planned and if the interventional cardiologist was willing to proceed with either radial or femoral access and had expertise for both (at least 50 radial procedures for coronary angiography or intervention within the previous year). The original sample size of 4000 was increased to 7000 by the RIVAL steering committee during the trial due to a lower-than-expected overall event rate for the primary outcome and because a sample size of 7000 would provide 80% power to detect a 25% relative risk reduction with a control event rate of 6% and a 30% relative risk reduction with a control event rate of 4% to 5%.

RIVAL enrolled 7021 patients at 158 hospitals in 32 countries. The patients were randomly assigned to radial access (n=3507) or femoral access (n=3514). The primary outcome was a composite of death, myocardial infarction (MI), stroke, or noncoronary artery bypass graft (non-CABG)-related major bleeding at 30 days. Secondary outcomes included death, MI, or stroke at 30 days; non-CABG-related major bleeding at 30 days; and major vascular access site complications.

There were no significant differences between the two groups with respect to either the primary or secondary outcomes that were related to death, MI, stroke, or non-CABG-related bleeding. The primary outcome occurred in 3.7% of the patients in the radial group and 4.0% of the patients in the femoral group (HR, 0.92; 95% CI, 0.72 to 1.17; p=0.50). There was, however, a difference in the rate of major vascular site complications, with fewer complications that were associated with radial access (1.4% vs 3.7%; HR, 0.37; 95% CI, 0.27 to 0.52; p<0.0001).

The researchers compared the two approaches in six prespecified subgroups: age (<75 and ≥75 years), gender, body mass index, PCI volume by operator, radial access volume by center, and diagnosis at presentation (non-STEMI and STEMI). The results were similar in all subgroups with two exceptions: a significant difference was observed in favor of radial access when performed at centers with the highest volume of radial access procedures (HR, 0.49; 95% CI, 0.28 to 0.87; p=0.015) and in patients with STEMI (HR, 0.60; 95% CI, 0.38 to 0.94; p=0.026).

Overall, RIVAL showed no significant benefit for radial access compared with femoral access in patients who presented with ACS. Reasons for this neutral result may include inadequate power to detect a difference of the magnitude that was observed. In the associated manuscript, the authors state, "RIVAL was underpowered to conclusively rule out moderate but important differences in the primary outcome. On the basis of the reported event rate of 4%, a sample of size of 17,000 patients would be needed to have 80% power to detect a 20% relative risk reduction in the primary outcome." Although the findings are neutral overall, clinicians may find the observations that radial access was associated with reduced rates of major vascular complications compared with femoral access and that the effectiveness of radial access appeared to be associated with expertise and volume to be helpful in clinical decision-making.

Further Reading: Jolly SS et al. *Lancet* 2011.

EVEREST Trial 2-Year Results Show Stability of Percutaneous MV Repair Between Years 1 and 2

Ted Feldman, MD, North Shore University Health System, Evanston, Illinois, USA, reported the 2-year results from the Endovascular Valve Edge-to-Edge Repair trial (EVEREST; NCT00209274), showing that percutaneous mitral valve (MV) repair is safe and durable with measurable clinical benefits and is a therapeutic option for select patients with significant mitral regurgitation (MR) [Feldman T et al. *New Engl J Med* 2011].

The EVEREST trial comprised patients with moderate/severe (3+) or severe (4+) MR who were candidates for MV surgery and compared percutaneous MV repair using the MitraClip device with MV surgery. The primary composite endpoint was freedom from death, surgery for mitral valve dysfunction, and grade 3+ or 4+ MR at 12 months, using an intention-to-treat (ITT) analysis. The primary safety endpoint was a composite of major adverse events within 30 days.

A total of 279 patients were randomly assigned in a 2:1 ratio to percutaneous repair (n=184) or surgery (n=95). At 2 years, 12 patients in the percutaneous arm (7%) and 12 patients in the surgical arm (12%) had missing data. Patients were well matched in terms of age and comorbidities, with the exception of history of congestive heart failure, which was more frequent in the percutaneous arm (91% vs 78%; p=0.005). About three-fourths of subjects had degenerative MR, and 27% had functional etiology. Ejection fraction was well preserved in both groups.