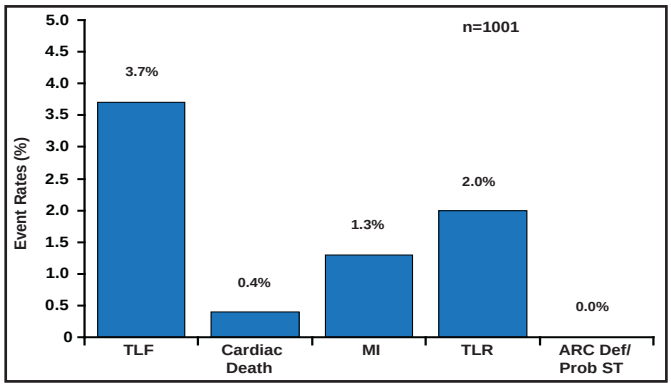
follow-up is required to demonstrate long-term efficacy and safety.

Figure 1. Main Analysis Cohort: 12-Month TLF, Cardiac Death, MI, and TLR.



Further reading: Yeung AC et al. *J Am Coll Cardiol* 2011; Mauri L et al. *Am Heart J* 2011.

The PLATINUM Trial: New Metal Alloy DES is Similar to a Predicate DES for Uncomplicated Elective PCI

A novel platinum-chromium everolimus-eluting stent (PtCr-EES) proved to be as safe and effective as the cobalt-chromium everolimus-eluting stent (CoCr-EES) in the 12-month Prospective, Randomized, Multicenter Trial to Assess an Everolimus-Eluting Coronary Stent System [PROMUS Element] for the Treatment of up to Two De Novo Coronary Artery Lesions Trial (PLATINUM; NCT00823212), the first large-scale, international, multicenter, prospective, single-blind, randomized trial of the novel stent [Stone GW et al. *J Am Coll Cardiol* 2011]. The PROMUS Element drug-eluting stent (DES) uses the same biocompatible, inert fluorocopolymer and antiproliferative agent as an earlier-generation CoCr-EES (PROMUS) but has a modified scaffold that is designed to improve delivery, vessel conformability, side branch access, radiopacity, radial strength, and fracture resistance.

In PLATINUM, 1530 patients who were undergoing percutaneous coronary intervention (PCI) of one or two *de novo* native lesions were randomized to receive CoCr-EES (n=762) or a PtCr-EES (n=768). The primary endpoint was the 12-month rate of target lesion failure (TLF), the composite of target vessel-related cardiac death, target vessel-related myocardial infarction (MI), or ischemia-driven target lesion revascularization (TLR) in patients who received at least one assigned study stent. The trial was powered to test for a noninferiority risk difference within 3.5%. Secondary endpoints included individual components of the primary endpoint, stent thrombosis, successful delivery and deployment of the stent without balloon rupture or stent embolization, and clinical procedural success, defined as a final lesion diameter <30% with TIMI 3 flow.

Among the 1530 patients who were enrolled and randomized, the mean age was 63 years, 28% was female, 23% had diabetes, and 24% had unstable angina. A total of 27 of the 762 patients (3.5%) who received CoCr-EES and 23 of the 768 patients (3.0%) who received PtCr-EES were lost to follow-up or withdrew consent. At 12 months, the primary outcome of TLF had occurred in 2.9% (21 out of 714) of the CoCr-EES versus 3.4% (25/731 patients) of the PtCr-EES group (risk difference +0.5%; 95% CI, -1.3 to 2.3%; p for noninferiority=0.001). Results were similar in the intention-to-treat analysis: 3.2% (23/737) of the CoCr-EES versus 3.5% (26/742) of the PtCr-EES group (risk difference +0.3%; 95% CI, -1.5% to 2.2%; p for noninferiority=0.0009). TLR and stent thrombosis rates were very rare and occurred equally with both stents (1.9% and 0.4%, respectively).

Findings from PLATINUM indicate that along with stainless steel and cobalt chromium, platinum chromium may now be considered an acceptable metal alloy for use in DES. Of note, however, the event rates were less than expected (and similar to the number that was lost to follow-up); thus, while statistical noninferiority was demonstrated, small differences between the stents can not be excluded. Longer-term follow-up and additional multicenter studies are indicated in patients with acute coronary syndromes and/or complex coronary anatomy to further assess stent deliverability and clinical outcomes in these important patient populations.

The RAPS Trial: Radial Artery Grafts are Associated with Greater Longer-Term Patency than SVGs

Aorta-to-coronary saphenous vein grafts (SVGs) are the most widely used technique in patients who undergo coronary artery bypass graft (CABG) surgery, but data from the Randomized Multicenter Radial Artery Patency Study (RAPS; NCT00187356) demonstrate that radial artery grafts have better long-term angiographic patency. Stephen Fremes, MD, MSc, University of Toronto and Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada, presented findings from the 5-year analysis of RAPS, a

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