than for tibial arteries. Compared with coronary DES, self-expanding struts are thicker, the drug-free interstices are wider, and the dosimetry per volume of plaque is lower. Thus, predicting the effectiveness of below-the-knee DES based on previous SFA trials may be deceptive.

2. Although limb salvage and relief of rest pain are the primary goals of critical limb ischemia therapy, we propose that extended arterial patency is an additional end point that deserves consideration. The mantra that “patency need only be maintained long enough to affect healing” is derived from observation that long-term bypass patency is suboptimal. Previous studies (referenced in the PaRADISE [Preventing Amputations Using Drug Eluting Stents] trial), demonstrated excellent short-term DES patency. Recently, Balzer et al. (2) reported that 83% of Cypher stents (Cordis Corp., Bridgewater, New Jersey) (n = 341) were patent at 18 months. Whereas bypass surgery demonstrates time-dependent decremental graft patency and limb salvage, data from the PaRADISE trial and Balzer et al. (2) suggests that stent patency and limb salvage remain nearly constant after the first 6 months. Thus, DES may facilitate long-term patency translating into fewer repeat interventions and reduced health care costs.

3. Reducing mortality in critical limb ischemia remains a significant challenge. However, a DES-centered endovascular strategy may offer significant improvement over current therapy. The 1-year mortality in the PaRADISE trial was 11%. The median age of death was 80 years (95% confidence interval: 74 to 86 years), which is comparable to expected actuarial survival. In comparison, first-year mortality in the BASIL (Bypass Versus Angioplasty in Severe Ischaemia of the Leg) trial (3) was 20%, and in the PREVENT III trial (4), mortality was 15% even though patients were a mean of 7 years younger. We postulate that PaRADISE’s apparent survival advantage is related to reduction in deaths from surgery, amputation, procedural complications, and more aggressive secondary prevention.

Contemporary evidence indicates that the time is right for an industry-sponsored U.S. Food and Drug Administration independent developmental evaluation designed to investigate the impact of DES on limb salvage, cost-effectiveness, and quality of life in patients with critical limb ischemia.

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Transradial Coronary Intervention Radiant or Brilliant?

We read with great interest the recently published review of Rao et al. (1) regarding the clinical benefits of using the transradial approach for percutaneous coronary interventions (PCI). The paper outstandingly demonstrates how deeply a technical modification might influence our current clinical practice. Despite these benefits, the paper attracts the reader’s attention to the low adoption rate of this technique that is primarily supplied by the fears and thoughts from the learning curve of the undevoted operators. In the current correspondence, we would like to extend the Rao et al. (1) discussion with the findings of 2 recent observations.

Rao et al. (1) cited and discussed 2 comprehensive meta-analyses of randomized comparisons between the transradial PCI and transfemoral PCI approaches (2,3). Although these studies demonstrated a significant reduction in bleeding- and access site-related complications, they failed to find a significant link between the frequency of adverse cardiovascular events or mortality. It should be noted that these analyses included studies performed predominantly in elective settings and thus the benefit of the higher-risk patients may have been concealed by the low-risk cases that may have formed the majority. In a recent meta-analysis of 12 studies involving 3,324 patients with ST-segment elevation myocardial infarction, we demonstrated that beyond the bleeding benefit, radial, when compared to transfemoral, approach reduced the risk of death, myocardial infarction, urgent revascularization, or stroke by 44% (odds ratio [OR]: 0.56 [95% confidence interval (CI): 0.39 to 0.79]; p = 0.001) and mortality by 46% (OR: 0.54 [95% CI: 0.33 to 0.86]; p = 0.01) (4).

Moreover, there were no differences in procedural times and in time to reperfusion between the 2 access routes. Fluoroscopic times were longer in cases of transradial PCI; however, there was significant heterogeneity among studies in these parameters.

Another trial that might add important observations to this topic is the RAPTOR (Radial Access versus conventional femoral PercTure: Outcome and Resource effectiveness in a daily routine) study (5). The RAPTOR study was a prospective, randomized, single-center trial to compare radial versus femoral access in an unsedected population. The study has demonstrated that an immediate, ad hoc switch to the transradial program is feasible for an interventional site with operators experienced in femoral access. The trial showed that transradial PCI was not associated with longer procedural or radiation times, nor with higher rates of access site failures. Procedural and fluoroscopic times and radiation doses were only greater in case of the diagnostic angiographies, but not for PCIs.

In conclusion, the use of transradial PCI is not only beneficial to reduce bleeding but also for ischemic complications and mortality in high-risk patients undergoing coronary interventions. The
RAPTOR study demonstrates that it is safe and effective to change our clinical practice even from one day to the other. Longer fluoroscopic times might be attributable to the manipulation during the diagnostic phase that can be significantly reduced by training and experience.

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Reply

We thank Drs. Komócsi and Aradi for their insight regarding our review (1) of transradial percutaneous coronary intervention (PCI). First, we agree that practice change from femoral to a radial approach is feasible. We changed to the radial approach while working in predominantly transfemoral catheterization laboratories. We also agree that procedure and fluoroscopy times, as well as access site crossover rates, can be reduced significantly with increased radial experience.

Second, they are correct that the mortality risk associated with bleeding may be dependent on the patient’s presentation (2). Their meta-analysis of studies comparing radial and femoral PCI in acute ST-segment elevation myocardial infarction (3) is provocative but does not provide definitive evidence that transradial PCI directly reduces mortality. Their analysis included both randomized and observational comparisons of radial and femoral PCI. This introduces confounding into the analysis because the radial approach is used more often in patients at lower risk for bleeding and ischemia (4), and subsequently who are at lower risk for mortality. In addition, transradial PCI directly reduces bleeding only at the vascular access site. Two studies (5,6) have demonstrated that isolated groin hematomas, the most common type of bleeding seen with transfemoral PCI, do not correlate with mortality. With the exception of preventing retroperitoneal hematomas or transfusion (7), it is difficult to explain the mortality reductions seen with transradial PCI in observational studies. A well-designed, randomized, international trial is still needed before one can definitively conclude that transradial PCI reduces mortality. The success of such a trial depends on the willingness of operators to randomize patients to either a radial or femoral approach, rather than relying on observational data to drive a major shift in clinical practice.

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