

created a bench test model to investigate the safety and efficacy of rotablation for BVS struts.

To create BVS and MS disruption models, a 3.0 mm Absorb BVS and Xience Prime metallic stent (Abbott Vascular) were deployed in silicone tubes, and then crushed using forceps. The silicone tubes were perfused with saline, and then the BVS and MS were pulverized using a rotablator with a 2.0 mm burr (Boston Scientific) at 210,000 rpm. Saline in the tube was collected following rotablation, and the particle sizes were immediately analyzed by the Electrical Sensing Zone method using a Multisizer 4e Coulter Counter (Beckman Coulter, Miami, Florida). We further performed optical coherence tomography before and after rotablation.

Optical coherence tomography observations of BVS showed its surface to be more smoothly pulverized compared with the MS (Figures 1A to E). Viewing the pulverized BVS under high magnification, shavings remained clinging to the surface (Figure 1F). Most of the pulverized BVS particles were <5 μm in diameter (smaller than red blood cell; 7 μm), and numerically comparable with those of the MS (BVS 98.5%; MS 99.3%) (Figure 2). These particles are small enough to pass through the coronary microcirculation and undergo phagocytosis (5). Rotablator for BVS strut seems to be effective and feasible, which can be a possible solution for major BVS fracture, acute recoil, or incompletely deployed BVS that cannot be dilated by high-pressure balloon angioplasty.

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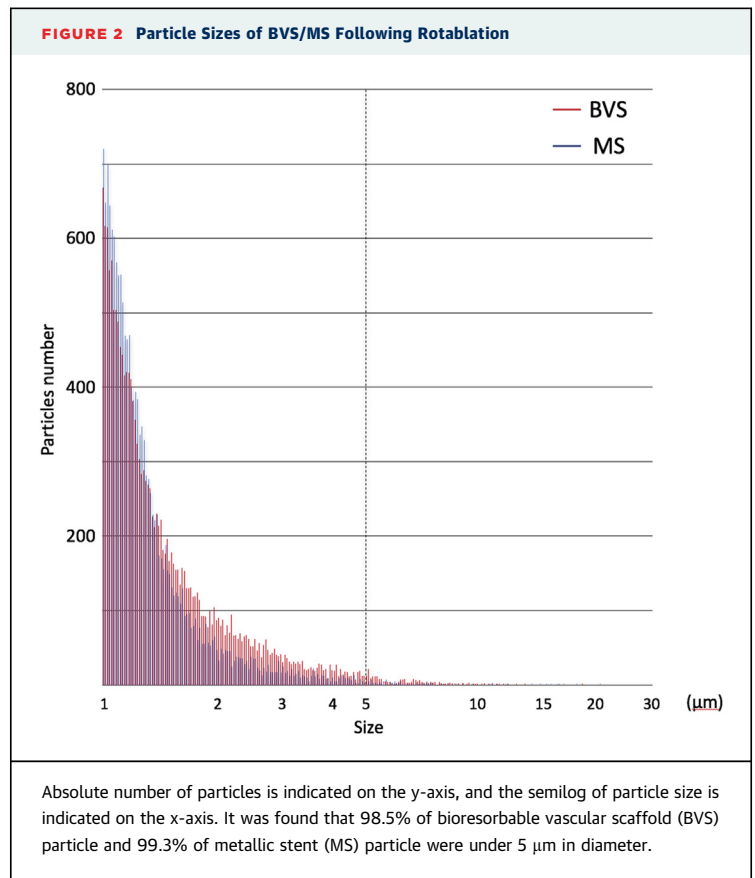
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Drug-Eluting Stents Are Effective in Women



Only Part of the Story?

I read with interest the results of the paper by Giustino et al. (1) to evaluate the safety and efficacy of new-generation drug-eluting stents in women undergoing complex percutaneous coronary artery revascularization. I wish to congratulate the investigators on undertaking this piece of work in such a

large cohort (n = 10,241) to help us improve our understanding of the outcomes of percutaneous coronary intervention in women. I was particularly encouraged to see improved results for newer drug-eluting stent platforms in terms of reducing major adverse cardiac events (defined as the composite of all-cause mortality, myocardial infarction, and target lesion revascularization at 3 years).

However, one of the concerns when treating women is the risk for bleeding, particularly when faced with patients who may be older and of relatively low weight compared with their male counterparts. This is reflected in bleeding risk predictor scores, which include female sex as an important predictive factor (2,3). Indeed, female sex carries even more weight in these validated scores than baseline anemia. Importantly, previous work suggests that even if data are adjusted to take into account age, body mass index, and type of antithrombotic therapy, female sex remains an independent predictor of bleeding (4). Furthermore, the investigators quite correctly state that women are at increased risk for problems such as access-site complications, but they do not provide us with the rate of occurrence of such events in their population.

As the investigators are well aware, the occurrence of bleeding after coronary intervention increases the risk for death and, importantly, is associated with not insignificant morbidity (5). This is important because of the effect on quality of life as well as the cost implications of a prolonged hospital stay. It is therefore difficult to fully appreciate the results presented in this present study when taken in such isolation. The inclusion of safety information about major adverse bleeding events should be described as a fundamental part of studies of this nature.

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REPLY: Drug-Eluting Stents Are Effective in Women



Only Part of the Story?

We appreciate the interest of Dr. Hoye in our study investigating the efficacy and safety of new-generation drug-eluting stents (DES) versus early-generation DES in women undergoing complex percutaneous coronary intervention (PCI) (1). Dr. Hoye's point is very well taken, as in the past, female sex proved to be strongly associated with increased risk for periprocedural vascular and bleeding complications (2). Unfortunately, such adverse events were not captured in the patient-level pooled dataset of the 26 randomized controlled trials included in this collaborative analysis. However, although the rates of vascular and bleeding complications are of concern in women undergoing coronary and structural percutaneous interventions, some considerations must be made.

First, not only have women been previously underrepresented in randomized controlled trials of cardiovascular devices, but they also constitute an underdiagnosed, undertreated, and underresearched population with considerable room for improvement (3). That being said, our findings supporting improved efficacy and safety of new-generation DES even in highly complex coronary anatomies is reassuring and should encourage physicians to treat women with high-risk anatomy with PCI, especially when they are not suitable for surgical revascularization.

Second, we should differentiate between in-hospital and out-of-hospital bleeding complications after PCI with DES. Although female sex was demonstrated to be among the strongest risk factors for periprocedural access-related and nonaccess-related hemorrhagic complications after PCI, its association with post-discharge bleeding is uncertain.