Analysis of drug-eluting stents data demonstrates safety, efficacy in on-and-off-label use

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The Cardiovascular Research Foundation (CRF) announced that results of the largest meta-analysis to date comparing mortality rates for drug-eluting stents (DES) versus bare metal stents (BMS) were published online June 15 in the journal *Circulation*. The study also compared the rates of myocardial infarction (MI) and target vessel revascularization (TVR).

The analysis—which includes approximately 190,000 patients from 56 studies—was performed by a team of researchers led by Ajay J. Kirtane, MD, Assistant Professor of Clinical Medicine at Columbia University College of Physicians and Surgeons; and an interventional cardiologist at NewYork-Presbyterian Hospital/Columbia University Medical Center; and Gregg W. Stone, MD, Immediate Past Chairman of the Cardiovascular Research Foundation; Professor of Medicine at Columbia University College of Physicians and Surgeons; and Director of Cardiovascular Research and Education in the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center.

Drs. Kirtane and Stone conducted two parallel meta-analyses examining DES vs. BMS use in both randomized, controlled trials and in observational registry analyses. The overall analysis represents the largest systematic overview of "real-world" (comprising both on-label and off-label) DES use to date and incorporates an overview of both the

published literature as well as several unpublished studies presented at major cardiovascular meetings.

"The findings from these parallel studies are striking," said Dr. Stone.

The meta-analysis of 22 randomized trials included more than 9,000 patients with recent follow-up from previously published trials. According to the results, "DES resulted in no overall differences in death and MI, with a greater than 50% decrease in subsequent target vessel revascularization procedures," said Dr. Stone, adding that these findings are consistent with both on-label and off-label use of DES.

And in the 34-study observational meta-analysis (involving more than 180,000 "real-world" patients), "DES resulted in significant 22% and 13% reductions in death and MI, respectively, with a similar reduction in TVR (46%) as in the randomized trials, even after adjustment for confounding variables," said Dr. Stone. "These data are reassuring that DES are safe and effective for a wide-range of patients that are able to take dual antiplatelet therapy for at least one year."

The findings were consistent and robust across a variety of study designs; trials that were included were required to follow patients for at least one year.

Dr. Kirtane remarked that these findings should help to reassure patients and physicians about the safety of DES in off-label use.

"One of the interesting aspects of this analysis is that it points to significant differences between results obtained from randomized trials and observational analyses. Nonetheless, even with the stated limitations of observational data, the bottom line from both randomized trials and observational analyses is consistent: we can reduce the need for repeat procedures and we do not appear to be harming patients with DES," he

added.

Source: Cardiovascular Research Foundation