Drug-eluting stents more effective than bare-metal stents in heart attack patients

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NewYork-Presbyterian Hospital and Columbia University Medical Center, together with the Cardiovascular Research Foundation (CRF), announced that its landmark study comparing the safety and efficacy of drug-eluting stents and bare-metal stents was published in the May 7 *New England Journal of Medicine*. The study, HORIZONS-AMI (Harmonizing Outcomes with RevascularIZatiON and Stents in Acute Myocardial Infarction), showed that in heart attack patients undergoing angioplasty, the use of paclitaxel-eluting stents reduces rates of target lesion revascularization (TLR) and binary angiographic restenosis when compared to the use of bare-metal stents after one year.

Additionally, the primary safety measure of major adverse cardiovascular events (MACE), including death, reinfarction, stent thrombosis and stroke established the non-inferiority of drug-eluting stents with respect to safety through one year.

The study was led by Dr. Gregg W. Stone, director of cardiovascular research and education in the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center; and professor of medicine at Columbia University College of Physicians and Surgeons. The research was sponsored and managed by the Cardiovascular Research Foundation with research grant support from Boston Scientific Corporation and The Medicines Company.

In the trial, the use of paclitaxel-eluting stents resulted in a significant reduction of ischemia-driven target-lesion revascularization (TLR) at 12

months (4.5% vs. 7.5%). TLR, which was the primary efficacy endpoint of the trial, refers to the rate at which a particular lesion re-narrows following stent implantation severely enough to require either a repeat angioplasty or bypass surgery operation.

The use of paclitaxel-eluting stents also resulted in a significant reduction in binary restenosis after 13 months, which is the rate at which the artery re-narrows at least 50 percent following implantation of the stent, and was the secondary efficacy endpoint of the trial. The paclitaxel-eluting stent had a rate of 10.0 percent and the bare-metal stent had a rate of 22.9 percent.

"Outcomes from prior registry and randomized trials of drug-eluting stents compared with bare-metal stents in heart attack patients have been conflicting. These results now provide definitive evidence that paclitaxel-eluting stents are superior in efficacy to bare-metal stents and have a comparable safety profile at one year," says Dr. Stone. "The findings from the HORIZONS-AMI trial will have a major impact on how decisions are made regarding drug-eluting and bare-metal stents in the highest-risk patients, those in the early hours of a heart attack. This study removes much of the uncertainty and concern about the efficacy and safety of drug-eluting stents in this clinical setting. Moreover, all of the patients in this trial will be followed long-term to ensure that these favorable results are maintained."

The HORIZONS-AMI trial, a prospective, open-label, multicenter, controlled study, enrolled 3,602 heart attack patients at 123 centers in 11 countries, 3,006 of whom were randomized to paclitaxel-eluting stents versus otherwise identical bare-metal stents.

Source: New York- Presbyterian Hospital (news : web)