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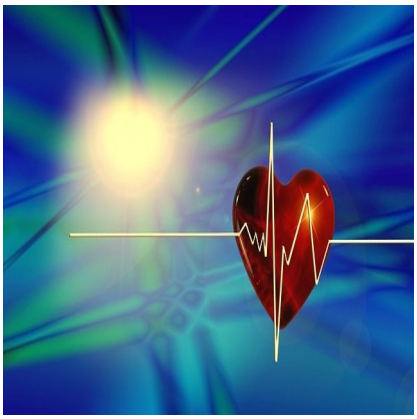
Drug-Eluting Stents, Heart Attack and Bleeding Risks: One-Year Results of ADAPT-DES Trial



Patients who receive a drug-eluting stent (DES) and demonstrate high platelet reactivity on clopidogrel are more likely to have blood clots form on the stent and to suffer a heart attack; however, these patients are less likely to develop bleeding complications. One-year results of the ADAPT-DES trial will be published online July 26, 2013, in *The Lancet*. The findings were first presented at last year's Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium.

ADAPT-DES is the largest study ever to explore the overall treatment implications of platelet reactivity on patient outcomes after successful coronary drug-eluting stent implantation. Researchers investigated the relationship between platelet reactivity during dual therapy with aspirin and clopidogrel and clinical outcomes such as stent thrombosis, major bleeding, and other adverse events.

The study enrolled 8,583 patients at 11 sites in the US and Germany who underwent a percutaneous coronary intervention (PCI) with at least one drug-eluting stent between January 7, 2008, and September 16, 2010. Researchers assessed platelet reactivity with the VerifyNow Aspirin, P2Y12, and IIb/IIIa tests. Patients were followed for one year to determine the relationship between platelet reactivity and subsequent events. At one year, stent thrombosis had occurred in 70 patients (0.8 percent), heart attack in 269 (3.1 percent), major bleeding in 531 (6.2 percent), and death in 161 (1.9 percent).

Platelet reactivity units (PRU), an index of platelet inhibition to clopidogrel, were measured by the VerifyNow P2Y12 test. High platelet reactivity, defined as a PRU of greater than 208, was present in 42.7 percent of patients. At one year, researchers found that high platelet reactivity was significantly associated with stent thrombosis (1.3 percent vs. 0.5 percent) and heart attack (3.9 percent vs. 2.7 percent), but was also found to be protective against major bleeding (5.6 percent vs. 6.7 percent). High platelet reactivity was also associated with one-year mortality (2.4 percent vs. 1.5 percent). However, because high platelet reactivity is also associated with other patient risk factors and baseline characteristics, multivariable modeling was also performed; it showed no independent association between high platelet reactivity and mortality.

"Results from the ADAPT-DES registry definitely demonstrate that high platelet reactivity after implantation of drug-eluting stents is an independent predictor of one-year stent thrombosis and heart attack, but it is also protective against major bleeding, both of which impact mortality," said lead investigator Gregg W. Stone, MD.

Dr Stone is professor of medicine at Columbia University College of Physicians and Surgeons and Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center. Dr. Stone is also co-director of the Medical Research and Education Division at the Cardiovascular Research Foundation (CRF).

"Because of the counteracting effects of ischemia and bleeding, platelet reactivity was not an independent predictor of one-year mortality. Therefore, overcoming high platelet reactivity with more potent antiplatelet agents is unlikely to improve survival unless the beneficial effect of reducing stent thrombosis and heart attack can be separated from the likely increase in bleeding that results from greater platelet inhibition," said Dr. Stone.

Dr. Stone added: "Platelet reactivity on aspirin was unrelated to stent thrombosis, heart attack, or death, but may be related to bleeding. This raises questions as to the utility of aspirin in patients treated with drug-eluting stents."

The ADAPT-DES trial was sponsored by CRF with research support from Boston Scientific, Abbott Vascular, Medtronic, Cordis, Biosensors, The Medicines Company, Daiichi Sankyo, Eli Lilly, Volcano, and Accumetrics.

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