DUAL ANTIPLATELET THERAPY (DAPT) COULD BE INDIVIDUALIZED

The DAPT Score - a Decision Tool to Predict Benefit and Risk of Extended Duration Dual Antiplatelet Therapy

BOSTON – NOVEMBER 10, 2015 – The Harvard Clinical Research Institute (HCRI) announced today the results of a new analysis which offers a strategy for individualizing the duration of dual antiplatelet therapy following percutaneous coronary intervention (PCI) with a coronary stent. Robert W. Yeh, MD, MSc, MBA, Director of the Smith Center for Outcomes Research in Cardiology at Beth Israel Deaconess Medical Center and the Medical Director of Trial Design at Harvard Clinical Research Institute, presented this research related to the Dual Antiplatelet Therapy (DAPT) Study at the American Heart Association (AHA) 2015 Scientific Sessions in Orlando.

Dr. Yeh and study investigators used the DAPT Study data to create a clinical decision tool (the DAPT Score). The DAPT Score was able to identify patients who derived the greatest benefit from continuation of dual antiplatelet therapy beyond 1 year, as well as those who were likely to be harmed. In the DAPT Study, 11,648 PCI patients who completed 12 months of dual antiplatelet therapy were randomized to continued thienopyridine (clopidogrel or prasugrel) plus aspirin versus aspirin alone. In the primary DAPT Study analysis published and presented in 2014, continued thienopyridine was associated with significant reductions in the co-primary efficacy endpoints of stent thrombosis and the composite of death, myocardial infarction and stroke. Continued thienopyridine therapy resulted in halving of the rate of future myocardial infarction compared with placebo, but increased moderate or severe bleeding. The DAPT Score, composed of 8 clinical factors, presented by Dr. Yeh and released online, distinguished between patients most likely to benefit without increased bleeding risk, from those most likely to have bleeding risks that exceed the expected benefit of continued thienopyridine therapy.
“It can be difficult for physicians to predict whether an individual patient will be helped or harmed with treatment, said Dr. Laura Mauri, Principal Investigator of the DAPT Study, Associate Professor of Medicine at Brigham and Women’s Hospital and Harvard Medical School in Boston. “There are large potential benefits - lowering future myocardial infarction risk by 50% or more, yet ideally one would avoid bleeding risk. With the DAPT Score, it is now possible to personalize treatment recommendations to those patients most likely to benefit and not bleed – and avoid treatment in those who may not benefit.”

“Until now, we have not had an evidence-based approach for assessing the optimal duration of dual antiplatelet therapy for individual patients. The DAPT Score is unique in simultaneously integrating predictors of treatment benefit and harm of anti-platelet therapy for individual patients after coronary stent procedures”, said Dr. Yeh.

The DAPT Score was developed to predict combined ischemic and bleeding risk for patients being considered for continued thienopyridine therapy in addition to aspirin beyond 1 year after coronary stent treatment. The Score was developed from the DAPT Study randomized trial data, in which patients were randomized to continued thienopyridine therapy (clopidogrel or prasugrel) vs. placebo. Patients were randomized only if they had not sustained a heart attack, stent thrombosis, stroke, repeat revascularization, or bleed, and had been adherent with medications during the first year. Patients receiving oral anticoagulation or with limited life expectancy were excluded. A web-based DAPT Score calculator is available at www.DAPTStudy.org.

About the DAPT Study Collaboration

The DAPT Study was conducted by the Harvard Clinical Research Institute (HCRI) through a public-private collaboration involving HCRI; four major stent manufacturers: Abbott (XIENCE V®), Boston Scientific Corporation (TAXUS®, PROMUS®), Cordis Corporation (CYPHER®) and Medtronic, Inc. (Endeavor®); the manufacturers of thienopyridine/antiplatelet medications: Bristol-Myers Squibb Company/Sanofi Pharmaceuticals Partnership (Plavix® (clopidogrel bisulfate)) and Eli Lilly and Company and Daiichi Sankyo Company, Limited (Effient/Efient® (prasugrel)); and the U.S. Food and Drug Administration (FDA). HCRI, which was responsible for the scientific and operational management of the DAPT Study and the independent analysis of the resulting data, received funding support from each of the drug and device manufacturers, the FDA and a grant from the U.S. Department of Health and Human Services.

More information about the DAPT Study is available at www.DAPTStudy.org.
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