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DISCUSSION OF THE DURATION OF DOUBLE ANTI-PLATELET TREATMENT OF DRUG COATED STENTS

The importance of taking Plavix (clopidogrel - a drug that helps prevent blood clotting) after receiving drug-eluting stents (DES) has received a lot of attention over the past few years. Not long after DES came into common usage, reports surfaced indicating that there is a long-term risk of sudden occlusion of the coronary artery with these stents, produced by the sudden formation of blood clots at the site of the stent. Sudden blockage of a coronary artery, of course, can have catastrophic results including heart attack and sudden death. The long-term use of Plavix is thought to substantially decrease this risk. Unfortunately, long-term Plavix therapy is not benign. Indeed, trauma or surgery while on Plavix can have devastating consequences. Some cardiologists refuse to allow their DES patients to stop Plavix even long enough to have elective surgery - placing the patient in an untenable position. So a major remaining question with the use of DES is: How long should Plavix therapy be maintained?

In an extraordinary hearing of the FDA in late 2006, the recommendation was to continue Plavix therapy for at least 12 months after DES. But recognizing that there was little data on which to base this recommendation, a strong plea was made to conduct a randomized clinical trial as rapidly as possible to answer the Plavix question once and for all.

Unfortunately, as reported by Shelley Wood for theHeart.org, nearly a year and a half after this FDA hearing that study is not even close to getting off the ground, let alone yielding useful results. (Wood's report is linked here, but registration is required.) Wood describes continued difficult "negotiations" (some might call it squabbling) between researchers at the Cardiovascular Safety and Research Consortium (located at Duke University), various government agencies, and manufacturers of DES, over the goals, design, size and duration of the proposed study. From the sounds of it, the study that everybody's waiting for won't be providing anything like definitive answers, for many years to come, on how long DES patients need to remain on Plavix.

This means that if your doctor is recommending DES, for the foreseeable future you're still going to need a long talk with your doctor about Plavix - specifically, how long will the doctor want you to take it, and what is to be done if it turns out you need surgery 8 months from now? Unfortunately, it appears the Plavix question will be looming over the use of DES for a long time to come.