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Discontinuation of Plavix (Clopidogrel):

This Is A Sample Letter That Is Sent To Physicians That Are Involved In The Care Of Our Patients That Have Received A Drug-Eluting Stent In The Past.

Re: Discontinuation of Plavix (Clopidogrel); in patients that have received a “drug-eluting” stent (includes the JJIS/Cordis Cypher stent, and the Boston Scientific/Sci-Med Taxus stent)

Dear Doctor:

Your patient underwent implantation of a “drug-eluting” coronary stent as part of his/her revascularization procedure. Coronary stents require the oral administration of combination anti-platelet agents (aspirin and clopidogrel) for a prolonged period of time after implantation, to avoid the development of stent thrombosis (ST). Such an event can be associated with a large myocardial infarction, and even death (related to sudden epicardial coronary occlusion). With all stents [“non-drug-eluting” (bare-metal) stents (BMS), and “drug-eluting” stents (DES)], the greatest risk occurs within the first 10-days after implantation (before the stent has become endothelialized). The risk of ST immediately after the initial implant is ~ 1% in patients on combination anti-platelet therapy, but much greater without the combined anti-platelet protection. It has been generally accepted that most patients will endothelialize BMS within a few weeks after implant, and the critical time to maintain dual anti-platelet therapy in these individuals will be for at-least the first month after implantation.

The PCI-CURE study (*Lancet: 358; August 2001*) determined that there was a lower incidence of death, myocardial infarction, and repeat revascularization in individuals that had continued their combination anti-platelet therapy for 1year post-stent implantation (as compared to those that received conventional combination anti-platelet therapy for only one month).

DES are the newest type of coronary stents, and have been implanted in more than 4 million individuals worldwide beginning with their introduction in 2003 up until the end of 2006. During this time, a DES was used in > 80% of patients. DES have shown the ability to decrease coronary target-lesion revascularization by > 50% (by reducing the overall restenosis rate to <3%) as compared to BMS. The long-term major adverse cardiac event rate with the use of a DES remains < 5% overall (includes the incidence of death, myocardial infarction, and repeat revascularization). DES have proven to be superior to BMS in specific lesion-types (chronic total occlusions, in-stent restenosis, aorto-ostial lesions, saphenous vein grafts, bifurcation lesions, and multi-vessel disease). Reports have surfaced regarding the development of very late ST at >1 year after stent implantation in a small number of individuals (incidence of ~0.5% to 0.6% per year in patients with DES). In many of these cases reported, the events occurred after the stented individuals had discontinued their combination anti-platelet therapy.

The CHARISMA trial, presented at the American College of Cardiology’s Annual Scientific Session in March 2006, and published in the New England Journal of Medicine reported an increase in the incidence of “moderate bleeding” in individuals taking both aspirin and clopidogrel [1.7%] (as compared to individuals taking only aspirin [1.3%]). This study included individuals without coronary stents, who were taking the medications for other indications (heart attack, stroke, etc.) Shortly after the release of this trial, the American College of Cardiology issued a reminder to its member cardiologists, that according to the 2006 ACC/AHA/SCAI Guidelines of Percutaneous Coronary Intervention: “the use of aspirin and clopidogrel in patients undergoing angioplasty with stent implantation remains a class I recommendation.” The long-term use of aspirin and clopidogrel in patients that have received DE S is a class IIb recommendation.

The exact mechanism by which a nidus for ST develops after DES implantation is not definitively known. Some subscribe to the theory of delayed healing with incomplete endothelialization and persistent stent strut exposure to the circulation. Other possible explanations include: an abnormal healing response – possibly with partial retraction of the vessel wall away from the stent, and possibly some form of a hypersensitivity reaction to the stent material or coating. The risk of ST is substantially increased in individuals that discontinue their dual antiplatelet therapy. In any event, the interventional cardiology community has been encouraged by the authorities to communicate the status and extent of the problem to the other physicians involved in these patients’ care.

If you believe that it may be necessary to discontinue Plavix (clopidogrel) in this patient:

Please contact our office immediately, so that we may discuss the matter with you in more detail. Please also be aware that a growing number of surgeons are becoming aware of the issues with “drug-eluting” stents. Many are willing to perform surgical procedures on these patients while maintaining their dual anti-platelet therapy, particularly where the risk of surgical bleeding related to a specific procedure may be relatively lower. We encourage you to consider this option to help afford our patients optimal cardiac protection. In all situations, the risk of procedural or peri-procedural bleeding in patients on aspirin and clopidogrel must be weighed against the risk of stent thrombosis encountered after the discontinuation of these medications.

Thank you for your time and attention to this matter. Please feel free to contact us for any additional information that you may require.

