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Drug-eluting stents after angioplasty have little relation to patients' probable benefit: study

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A new study finds that the use of drug-eluting stents after angioplasty bears little relationship to patients' predicted risk of restenosis (reblockage) of the treated coronary artery, the situation the devices are designed to prevent. In an *Archives of Internal Medicine* paper receiving early online publication, a multi-institutional research team reports that the devices are used in treating more than 70 percent of patients at low risk of restenosis. Since patients receiving these stents need to take costly anticlotting medications for at least a year – medicines that also have clinical risks – the benefits of drug-eluting stents may not outweigh the risks, inconvenience and costs of the devices for those patients. In addition, the authors note, reducing unnecessary usage of drug-eluting stents could significantly cut U.S. health costs.

"Both drug-eluting stents and bare metal stents help prevent reblockage of the coronary arteries, and drug-eluting stents further reduce that risk by inhibiting regrowth of tissue within the stent," explains Robert Yeh, MD, MSc, of the Massachusetts General Hospital (MGH) Heart Center, the study's corresponding author. "While these procedures can save lives during an acute heart attack and improve the quality of life for many patients, being more sensible in our application of this technology could lead to substantial savings with minimal clinical impact."

Coronary stents are tube-shaped wire scaffolds designed to prop open a coronary artery after a blockage has been removed by angioplasty.

Coated with agents that prevent the growth of tissue around the stent, drug-eluting stents were introduced in 2003 to prevent the restenosis that occurred around some bare metal stents. By 2005 drug-eluting stents were used in 90 percent of all angioplasty procedures, and while their usage subsequently declined, 75 percent of U.S. angioplasty patients currently receive the devices. Costs to Medicare alone from the use of drug-eluting stents – including costs for the devices themselves and for required long-term treatment with two antiplatelet drugs – were around $1.5 billion annually between 2002 and 2006.

The current study was designed to investigate how drug-eluting stents are being used in clinical practice, particularly whether their usage was focused on patients most likely to benefit from their effects. The investigators analyzed data from the National Cardiovascular Disease Registry (NCDR) of the American College of Cardiology to determine rates of drug-eluting stent usage among U.S. physicians, any association between stent use and patients' predicted risk of restenosis, and the potential impact of reducing usage among low-risk patients. Each patient's risk of restenosis was calculated using a model incorporating variables such as the presence of diabetes, the diameter of the treated artery and length of the initial blockage, and other clinical and demographic factors.

Focusing on data from the NCDR CathPCI Registry, the largest U.S. clinical registry of patients undergoing cardiac angioplasty, the investigators analyzed information on the treatment of 1.5 million patients at more than 1,100 U.S. hospitals between January 2004 and September 2010. Among those patients, only 13 percent were categorized as being at high risk of restenosis, while 44 percent were at moderate risk and 43 percent were low-risk. Overall, 77 percent of patients received drug-eluting stents: 83 percent of high-risk patients, 78 percent of moderate-risk patients and 74 percent of low-risk patients.

Among low-risk patients, the authors found, at least 25 and as many as 130 patients would need to be treated with drug-eluting stents instead of less expensive bare metal stents to prevent the need for a single repeat procedure. Physician usage patterns varied greatly, with some doctors using drug-eluting stents rarely, while others used the devices for virtually every procedure. The investigators calculated that reducing by 50 percent the use of drug-eluting stents in low-risk patients could save more than $200 million in U.S. health costs annually, even after accounting for a modest increase in the number of patients requiring a second angioplasty procedure.

In addition to cutting financial costs, reduced use of drug-eluting stents would prevent complications, such as increased risk of bleeding and the need to delay elective surgery, associated with the year-long antiplatelet treatment recommended for patients receiving the devices. Use of bare metal stents calls for only one month of antiplatelet treatment in stable patients. The authors note that, since both the costs and risks of antiplatelet therapy are born by patients, incorporating assessment of restenosis risk into regular practice could help patients and physicians make better-informed decisions about the best therapeutic strategy to pursue.

"The critical challenge in using stents is to be sure the decision reflects the patient's preference, rather than the physician's," says co-author John Spertus, MD, MPH, clinical director of Outcomes Research at Saint Luke's Mid America Heart Institute in Kansas City, Missouri. "If half the patients who find they are at low risk for restenosis choose bare metal stents to avoid the costs, bleeding risk and other complications associated with dual antiplatelet therapy, we could generate significant savings while better respecting patients' preferences." Spertus and other members of the research team are developing a study to examine whether improved understanding by patients and physicians of the risks and benefits will lead to usage patterns more in line with patients' actual

risk level.

Yeh adds, "We need to start thinking more about who is really going to benefit from drug-eluting stents, or really any technology, before we utilize it. Developing predictive clinical models that can help with risk/benefit assessment and finding ways to more effectively integrate those tools into our busy clinical routine are important challenges we are trying to overcome." Yeh is an instructor in Medicine at Harvard Medical School, and Spertus is the Lauer/Missouri Endowed Chair and Professor of Medicine at the University of Missouri–Kansas City.

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