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Drug therapy more cost-effective than angioplasty for diabetic patients with heart disease

STANFORD, Calif. — Many patients with diabetes should forego angioplasties for heart disease and just take medicine instead, according to a new National Institutes of Health study led by Stanford University School of Medicine researcher Mark Hlatky, MD.

Previous research had shown that patients with type-2 diabetes and mild-to-moderate heart disease have no reduction in risk for heart attacks, strokes or death if they have an angioplasty compared with simply taking the right medications. The new study shows that there's substantial cost savings in sticking with drug treatment, with an average savings of \$11,000 per patient over four years.

"For patients with relatively mild symptoms of heart disease, angioplasty is clearly more expensive and it's clearly not more beneficial," said Hlatky, professor of health research and policy and of cardiovascular medicine, who will present the new findings Nov. 17 in Orlando at the annual meeting of the American Heart Association. The report will be published online that same day in the journal *Circulation*.

The analysis described in the new paper is an example of the sort of comparative effectiveness research that the federal government is now promoting as critical for successful health-care reform.

The data come from the NIH's Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes study, called BARI 2D, which tracked the health of more than 2,000 patients for five years. During the trial, the patients all received intensive drug therapy according to accepted clinical guidelines, with use of statins, aspirin, beta-blockers and either ACE inhibitors or angiotensin-receptor blockers. The cost-effectiveness findings are based on the accumulated costs over a four-year period.

The earlier findings, on effectiveness of angioplasty and bypass surgery on death, heart attacks and strokes, were published June 11 in the New England Journal of Medicine.

Angioplasty had been compared with drug therapy in the COURAGE trial funded by the U.S. Department of Veterans Affairs and industry sponsors, including several pharmaceutical companies. That trial, published in NEJM in March 2007, concluded, as did the BARI 2D study, that for patients with mild-to-moderate heart disease symptoms, angioplasty and drug treatment are equally effective at preventing subsequent heart attacks and death.

The NIH study focused on patients with type-2 diabetes, as they have a higher risk of cardiovascular disease than those without diabetes and have greater risk of heart attack and death from heart disease even if their symptoms are relatively mild. The study was funded by the National Heart, Lung and Blood Institute and the National Institute of Diabetes and Digestive and Kidney Diseases — both part of the NIH — along with the pharmaceutical and medical-device companies Abbott Laboratories, Astellas Pharma, GlaxoSmithKline, Lantheus Medical Imaging, Merck and Pfizer.

The conclusion that for diabetic patients with mild-to-moderate symptoms, medication works as well as angioplasty and at far less expense comes as no big surprise, said Hlatky, but it might go against the grain for many patients and doctors.

"Once you see a blocked artery on an angiogram, there's an overwhelming desire to fix it," said Hlatky. "You want to see it look better, so you want to go open it up — but what's really important is the patient's risk of dying and stroke. And modern medical therapy is really effective, and works just as well as angioplasty for a lot of patients."

He noted that the current health-care reimbursement system encourages the use of procedures over drug treatment. He also said some patients have the mistaken belief that they won't need medications if they have a procedure to "fix" a blocked coronary artery. "Patients with diabetes and heart disease need to be on effective drug treatments whether or not they have a procedure."

The researchers assessed the costs of the different approaches by counting up medical bills over the first four years of the study, including charges for hospitalizations, doctors' visits, drugs, tests and nursing home placements. The average cost of treatment for all patients in the study was \$70,000 over four years.

Additional findings: bypass and diabetes treatments

The study also assessed the cost effectiveness of bypass surgery and two different approaches to treating diabetes.

Bypass surgery is much more costly than drug treatment, running \$20,000 more over four years on average. But while surgery is much more expensive than drug treatment, for patients with severe heart symptoms it appears to be cost-effective — since people with more severe coronary disease suitable for bypass surgery were significantly less likely to have a heart attack or stroke, or die than patients treated with drugs alone.

The two different approaches to diabetes that were studied — drugs that improve the body's response to insulin versus drugs that increase the delivery of insulin — had comparable costs over four years. BARI 2D had previously shown that medical effectiveness of these approaches to drug treatment was similar too.

"For the two diabetes treatments, there was no difference in heart attack or death, and no difference in cost. It comes down to preference," said Hlatky. For example, patients who dislike injections might favor the insulin sensitization treatment, which relies on pills instead of shots.

The NIH plans to continue gathering and analyzing data from these patients in the coming years. "There could be longer-term effects that aren't yet apparent," said Hlatky.

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