Bypass Surgery Superior For Diabetics, Those With Heart Disease

Adults with diabetes and multi-vessel coronary heart disease who underwent cardiac bypass surgery had better overall heart-related outcomes than those who underwent an artery-opening procedure to improve blood flow to the heart muscle, according to the results from an international study. The research was supported by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health.

The study compared the effectiveness of coronary artery bypass graft (CABG) surgery with a non-surgical procedure known as percutaneous coronary intervention (PCI) that included insertion of drug-eluting stents. After five years, the CABG group had fewer adverse events and better survival rates than the PCI group.

Principal investigator Valentin Fuster, M.D., Ph.D., of Mount Sinai School of Medicine in New York City, will presented the study findings at the American Heart Association's annual meeting in Los Angeles. The findings will appear online in The *New England Journal of Medicine*. "These study results confirm that bypass surgery is a better overall treatment option for individuals with diabetes and multi-vessel coronary disease and may assist physicians' efforts to prevent cardiovascular events such as heart attacks and deaths in this high-risk group," explained Gary H. Gibbons, M.D., director of the NHLBI.

In coronary heart disease, plaque builds up inside coronary arteries. This often leads to blocked or reduced blood flow to the heart muscle and can result in chest pain, heart attack, heart failure, and/or erratic heartbeats (arrhythmia). In 2010, nearly 380,000 Americans died from coronary heart disease. Approximately 25 to 30 percent of patients needing CABG or PCI have diabetes and multi-vessel coronary heart disease. In the United States, more than one million procedures (CABG and PCI) are performed each year to restore circulation to patients with blocked arteries.

In CABG, surgeons try to improve blood flow to the heart muscle by using a healthy artery or vein from another part of the body to bypass a blocked coronary artery. PCI is a less invasive procedure in which blocked arteries are opened from the inside with a balloon. The type of stent used in the study, called drug-eluting, is coated with medicine that is slowly and continuously released to prevent an opened artery from becoming blocked again.

The study, called *Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM)*, involved 140 international centers and a total of 1,900 adults enrolled from 2005 to 2010. The participants had diabetes and coronary heart disease that involved narrowing of multiple blood vessels, but not the left main coronary artery, which usually requires

immediate treatment with CABG.

At each clinical site, a team of specialists in neurology, heart disease, diabetes and general medicine screened potential participants to ensure that they were eligible for both CABG and PCI. Those who were selected for the trial were randomly assigned to receive one of the interventions. As recommended by international guidelines for patients who receive drug-eluting stents, the PCI group also received anti-clotting therapies. A drug called abciximab was administered intravenously during the procedure, and clopidogrel was given orally for at least 12 months after the procedure, accompanied by aspirin for those who could tolerate it. Study participants were followed for at least two years.

During the trial, participants received standard medical care for all major cardiovascular risk factors such as high LDL cholesterol, high blood pressure and high blood sugar. Participants also were counseled about lifestyle choices such as smoking cessation, diet, and regular exercise.

After five years, the CABG group had a lower combined rate of strokes, heart attacks, and deaths (18.7 percent) than the PCI group (26.6 percent). Strokes, which are a well-known risk of bypass surgery, occurred slightly more often in the CABG group (5.2 percent) than in the PCI group (2.4 percent). However, more people died from any cause in the PCI group (16.3 percent) than in the CABG group (10.9 percent). The survival advantage of CABG over PCI was consistent regardless of race, gender, number of blocked vessels, or disease severity.

"The advantages of CABG over PCI were striking in this trial and could change treatment recommendations for thousands of individuals with diabetes and heart disease," said Fuster.

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