Heart bypass surgery better than angioplasty for certain patients, study shows

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After three years working with investigators from 10 different clinical trials around the world from Brazil to London to Pittsburgh, Stanford University School of Medicine researchers have pooled enough individual patient data to compare the effectiveness of coronary artery bypass surgery with the less-invasive angioplasty procedure on specific groups of patients for the first time.

Results of the study that looked at raw data from almost 8,000 research subjects show that for patients suffering from multi-vessel coronary artery disease who have diabetes and for patients older than 65, coronary artery bypass graft may be a better treatment choice than percutaneous coronary intervention (commonly known as coronary angioplasty), the technique of using balloons or stents to widen narrowed or obstructed blood vessels. In patients 55 years and younger, PCI may be the best choice.

"Whether you have diabetes really makes a big difference," said lead investigator Mark Hlatky, MD, professor of health research and policy and of cardiovascular medicine at Stanford. "Over several years there's a much lower rate of death with bypass surgery. The patient's age was the other major factor that affected outcomes, and this was a bit of a surprise."

The study, which will be published online in *The Lancet* on March 19, is a powerful example of the "comparative effectiveness research" for which the federal government recently allocated $1.1 billion from the

economic stimulus package. For about a decade, there's been growing concern that little research is available comparing various treatment courses for a variety of ailments from mild depression to back pain to heart disease, limiting the ability to make medical treatment decisions based on sound scientific evidence.

This study clearly shows the benefits of one course of treatment for specific sets of patients with coronary heart disease over another. For patients with diabetes, the mortality rate after a five-year follow-up was 12 percent for those who had bypass surgery compared with 20 percent for the angioplasty procedure. For patients older than 65, the mortality rate was 11 percent for those who had bypass compared with 15 percent for those who had angioplasty.

"This is the kind of research we're hoping to have more of so that clinicians and policymakers and patients can make informed decisions," said Douglas K. Owens MD, senior investigator at the Veterans Affairs Palo Alto Health Care System and professor of medicine at Stanford.

Hlatky added, "Traditionally the goal of clinical research has been to determine if a particular treatment works better than a placebo. Relatively little research has been done to determine if one active treatment is better than another."

Because of soaring rates of coronary artery disease, Americans now average nearly 250,000 bypass surgeries and more than 660,000 angioplasty procedures annually, totaling more than $100 billion in medical costs. With such high stakes, making informed decisions is a higher priority than ever, researchers say.

The Stanford study supports previous findings that long-term mortality is similar after bypass or angioplasty for the average patient with multi-vessel coronary artery disease, but goes one step further to check

whether this overall result is also true in most patient subgroups, such as women, smokers and patients with hypertension. Rarely is research broken down into these sub-group categories.

David Taggart, MD, PhD, professor of cardiovascular surgery at the University of Oxford, refers to the study as "the most definitive and authoritative analyses" of randomized trials comparing bypass surgery to angioplasty in an accompanying editorial, also scheduled to be published online in the March 19 Lancet. What is so significant, he writes, is that this study was able to compare high number of patients by pooling research from 95 percent of available randomized trials.

"This was the right time to do the study," Hlatky said. "There was a first wave of studies in which PCI was done using just balloon angioplasty, and then a second wave of studies in which PCI was done using bare-metal stents. We now have long-term outcome data from these studies, which is what we need to provide a fair comparison of PCI with bypass surgery." The next generation of studies will include angioplasty done with drug-eluting stents. None were included in this study because long-term follow-up is not yet available.

Hlatky said the idea for pooling raw individual patient data rather than simply using published results from multiple randomized trials of surgery and angioplasty was first proposed in 1995 by Stuart Pocock, PhD of the London School of Hygiene and Tropical Medicine, the senior author of the study.

"I attended a meeting in a dingy hotel meeting room in Anaheim where Stuart tried to get the clinical trial leaders at the time - from just a few balloon angioplasty trials - to collaborate and pool individual patient data to compare bypass surgery and angioplasty," Hlatky said. "The timing wasn't right, so the study wasn't begun.

"Ten years later, when we wanted to assess whether patient characteristics might affect the outcomes of bypass surgery and angioplasty, I remembered Stuart's proposal, and realized the best way to answer this question was to resurrect the idea of a pooled study from all the major trials. That was the only way we'd be able to perform a very detailed analysis of how individual characteristics affected the choice of the best treatment. In the intervening 10 years, the value of collaborative analyses has become more widely accepted, so the timing was right."

Legitimate concerns about patient privacy and questions concerning data ownership in collaborative studies needed to be worked out, Hlatky said. The lead investigator from one trial had died, and the data were thought to be lost, but another investigator from the study found a copy.

"It took a lot of discussion to establish this collaboration," Hlatky said. "While it would have been nice to travel to France, England and Brazil, instead we got together at the large international cardiology meetings in New Orleans and Orlando and Vienna. Once we were able to sit down together, everyone saw the value of working together to get information that simply wouldn't be possible to obtain any other way.

"It took some time to get individual patient data from all the participating trials, but it was worth it because the pooled analysis is much more valuable if it's based on essentially all the data. In the end we were able to analyze data from 95 percent of all the patients worldwide with multi-vessel coronary disease enrolled in a clinical trial of bypass surgery and angioplasty."

After the data were collected, the researchers then had to standardize the results in order to be able to compare "apples to apples," Hlatky said, due to various differences used in data collection methods.

In future studies, the researchers hope to analyze the new results from

their study to help understand why bypass is more effective for treating diabetes patients and older patients.

"We're not really sure of why surgery was better for these groups of patients," Hlatky said. "It's a very important and provocative observation that needs to be investigated further."

Source: Stanford University Medical Center (news : web)