Some Bypass Surgery Unnecessary

Results from an NHLBI clinical trial suggest that 25,000 potential bypass patients should not have the surgery

As many as 25,000 heart disease patients a year who now are thought to be good candidates for coronary artery bypass surgery might not need the operation, according to a newly completed study by the National Heart, Lung, and Blood Institute (NHLBI). Lloyd Fisher, a statistician at the University of Washington and the director of the study's coordinating center, says that these patients "pay no penalty for postponing surgery until their symptoms worsen."

Nonetheless, Fisher cautions, the study's results will almost certainly be controversial. "There is no doubt that there will be differences of opinion on the meaning and interpretation of the data," he remarks. In particular, the NHLBI results are different from those of a similar European study that was completed last year. These conflicting conclusions, says Eugene Passamani of the NHLBI, "are going to be very difficult to reconcile."

The NHLBI's Coronary Artery Surgery Study (CASS) began in the early 1970's and cost a total of $24 million. It was meant to determine whether bypass surgery prolongs life in patients with chest pains that are not incapacitating or in patients who have had at least one heart attack but who have no other symptoms of heart disease. Bypass surgery is clearly effective in relieving the characteristic chest pain of heart disease, but almost from the moment the operation was introduced in the late 1960's, medical scientists have asked whether it also saves lives.

It is estimated that 159,000 patients in the United States had bypass surgery in 1981 at a cost to the nation of $2.5 billion to $3 billion.

Within the past 5 years, two randomized controlled clinical trials have established that bypass surgery definitely prolongs the lives of patients with blocked left main coronary arteries—the main vessel bringing blood to the heart. In addition, one of these studies, the European Coronary Surgery Study, concluded that patients with three blocked coronary arteries and some patients with two blocked arteries might also live longer if they have bypass surgery. Since these European results were announced last year, cardiologists have tended to recommend surgery for heart disease patients with two or three blocked arteries, even if their symptoms are quite mild.

The CASS study was designed to specifically look at patients with mild symptoms of heart disease, comparing surgery to drug treatment. The study consisted first of a registry of 24,959 patients who were carefully characterized and who have been followed each year since CASS began. Those patients in the registry who were no more than 65 years old, who did not have narrowed left main coronary arteries, and who had mild to moderate angina or who had had at least one heart attack already but had no angina were eligible for the clinical trial. Those patients consisted of only 12 percent of the total registry. But they were the patients for whom the benefits of immediate surgery were unclear. These patients were offered a chance to participate in a randomized controlled trial comparing bypass surgery to medical treatment. Only 780 patients, or one-third of those eligible, agreed to the randomization, but the rest were followed anyway to see whether those who agreed to participate were different in any way from those who did not.

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The results are that there is no difference in mortality between those who were treated medically and those who were treated surgically. Moreover, patients who declined to have their treatment decided randomly were no different from those who participated in the randomized trial. It is now 6 years since the study began and 90 percent of the medically treated patients and 92 percent of the bypass patients are alive. The surgically treated patients had greater relief from angina, could exercise longer, and took fewer drugs. But they were hospitalized more often. And—most tellingly—there was no difference between the two groups of patients in the amount or type of recreational activity that they engaged in or in the number who returned to work. Moreover, angina gradually worsened with time in both groups. About 5 percent of the medically treated patients per year found their chest pains so much worsened that they elected to have bypass surgery.

The importance of the CASS results, says Passamani, is that they should relieve some of the pressure patients and doctors feel to go immediately to bypass surgery at the first symptom of heart disease. "What the CASS results show is that there is no penalty for waiting. The next event is likely to be a worsening of the angina, not death," Passamani says.

But if 5 percent of these patients per year go on to have bypass surgery and if the operation does not seem to decrease their life expectancy, why not just go ahead and have it at the first sign of heart disease? Thomas Killip, who is chairman of the Department of Medicine at Henry Ford Hospital and chairman of the CASS Steering Committee, remarks, "The argument from the CASS data is that perhaps there is a better time."

Since atherosclerosis progressively worsens anyway and patients may go on to have more than one bypass operation, it becomes important to carefully choose the time for the first operation. "As any surgeon could tell you, a second operation is more fraught with hazard, is technically more difficult, and is sometimes less successful," Killip says.

The major concern of the NHLBI scientists, however, is how to reconcile their results with those of the European study. They suspect that the European patients might have been sicker than the Americans because the trend in Europe is not to do bypass surgery for almost symptomless patients. Another possibility is that the European study, which was started a few years before the American one, used less effective medical treatment. Drugs to treat angina are constantly improving, and the difference in the European study was in the survival rates of the medically treated patients—the data from the surgically treated European patients are virtually superimposable with the American surgical data.

Nonetheless, the European results do present a problem and are one reason so many of the NHLBI investigators preface their remarks about the American trial with comments like, "If our results are accepted by the medical community." Passamani says, "You can be sure that the differences between the two studies will be vigorously dissected by our scientific community."

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