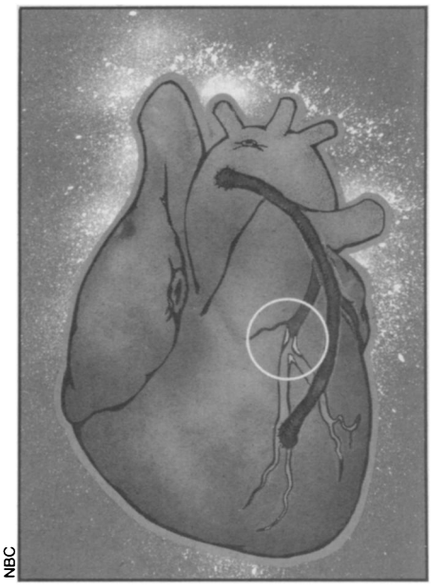
THE BYPASS BOOM

When is coronary artery bypass surgery reasonable? Long-term studies are providing physicians with conflicting answers.

BY JULIE ANN MILLER

"I don't care what you may have read in the Wall Street Journal, you need this operation." This may sound like a strange opening for a pep talk from a surgeon to his patient the night before open-heart surgery, but heart surgeons have become sensitive to newspaper reports that coronary artery bypass operations often do no good. Performed on more than 70,000 patients in the United States last year, the delicate and traumatic procedure has become routine in many hospitals. Yet the value of the operation is just being charted.

Long-term studies following many patients, some treated medically and others surgically, will eventually detail which patients will benefit from coronary artery bypass operations. Some studies are just getting off the ground; the results of others have already begun to trickle in.



NBC

Bypass carries blood beyond the narrowed coronary artery (circle) to heart muscle.

Today's heart patients, however, cannot wait for the results of a five-year study. So from preliminary results and the experience of hospitals during ten years of bypass operations, medical researchers are trying to distill guide rules. From January 1967 to April 1977, about 450 medical articles were published on surgery for coronary artery disease. While there are a few areas of agreement, a large field of sharp disagreement remains. Much of the dispute rests on the value of different types of studies.

Channeling blood to deprived areas of the heart is the idea behind bypass surgery. Coronary artery disease deposits fatty and fibrous material on the walls of vessels that carry blood to heart muscle. These deposits can partially or completely obstruct blood flow, and thus deprive muscle areas of oxygen. The disease begins in early childhood and, when established, progresses at a variable and unpredictable rate. For most of its reign, coronary artery disease is asymptomatic. Eventual recognizable symptoms are heart pain, heart attack, serious unevenness in heartbeat rhythm, congestive heart failure or premature death.

The oxygen-deprived human heart must inevitably work better if new blood is provided. That is the hypothesis his group has adopted, W. Dudley Johnson, one of the developers of the bypass operation, told a symposium on cardiac surgery. In the most common procedure a piece of vein about 2 millimeters in diameter is taken from the patient's leg and stitched to the healthy segment of the coronary artery beyond the blockage. The other end is stitched to the aorta, a larger blood vessel. "This is the most highly technical of any cardiac surgery, and I've been watching for 30 years," University of Wisconsin cardiologist George G. Rowe told SCIENCE NEWS. "All you have to do is get a stitch out of place to get restriction. If you don't do it right, it won't do."

The technique of angiography (also called coronary arteriography) allows physicians to finely map the blockages in the coronary arteries and to plan exactly where to construct bypasses. An injected dye reveals (on X-rays) vessels as small as 0.5 millimeter in diameter. Where an artery is completely blocked, the dye appears to dead-end. Angiograms also show that blood may find alternate routes through collateral blood vessels to supply the area of muscle previously served by the blocked vessel.

The pattern and degree of the blockages clearly influence both the severity of the disease and the value of bypass surgery. Cardiologists speak of single, double and triple vessel disease to describe how many of the three major coronary arteries are more than half blocked. Two of the coronary arteries fork from a vessel called the

Over 400,000 coronary arteries bypassed

Coronary artery bypass surgery is a big business. In the United States in 1977, the hospital bill approached $1 billion: more than 70,000 bypass operations at about $12,500 each. But coronary artery disease is a big problem. Almost half of the deaths in this country result from that disease. At 650,000 deaths annually, coronary artery disease kills almost twice as many people as cancer, the next largest killer.

Is this expensive surgical procedure the best response to the disease? Although more than 400,000 operations have been done in the last decade, and coronary bypass procedures may soon be the most common adult elective surgery, much remains unknown about its effectiveness compared with nonsurgical treatment. Critics suggest the method of inquiry has been defective. "The bypass mills continue to report a torrent of anecdotal and inadequately controlled series," says David H. Spodik of St. Vincent Hospital in Worcester, Mass. And there is no equivalent of the Food and Drug Administration to insist that a surgical procedure, like a medicine, be proved effective before it is put on the market.

Today U.S. hospitals have surgical teams with the potential for doing coronary bypass procedures on 150,000 patients a year. Will they fill those operating tables? More than 5 million men between the ages of 40 and 60 now have some coronary artery disease, according to the National Institute of Heart, Lung and Blood. Hospitals may soon come under external pressure to increase the number of bypass operations performed. Because survival rates are better at hospitals doing large numbers of heart operations, the Department of Health, Education and Welfare has recently published draft regulations that suggest existing open-heart surgery centers perform at least 200 operations a year and require new ones to be able to do 350 before they go into business. Donald W. Miller and colleagues at the University of Washington in Seattle conclude a survey of cardiovascular surgeons: "It is ironic that we are developing a complex, mass-produced operation to treat a disease that is largely a product of a society which has made such a procedure possible."

left main coronary artery. Thus, a blockage there is more severe than in another single vessel.

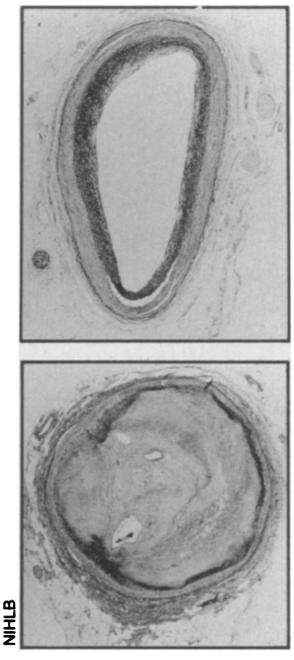
The goal of surgery is to remedy any or all of the clinical manifestations of coronary heart disease. In a review in the March CIRCULATION, Henry D. McIntosh and Jorge A. Garcia from the cardiology section of Baylor College of Medicine in Houston conclude that the available data do not indicate that heart attacks, irregular heartbeat or congestive heart failure are prevented by the surgery, although a few studies have claimed an effect. Most of the research evaluating bypass surgery focuses on pain relief and prolongation of life.

One area of general agreement is that coronary bypass operations can dramatically relieve pain. In several studies, at least 75 percent of surgery patients were completely free of pain in the period after surgery, and the "quality of life" improved for some time in up to 90 percent of the patients. McIntosh and Garcia point out, however, that the initial, highly satisfactory improvement is not always lasting. In four studies there was a gradual deterioration in pain relief over two to four years.

The mechanism of the pain relief is still under discussion. Michael Lesch of Northwestern University Medical School and Richard Gorlin of Mount Sinai School of Medicine say in a review article in the January JOURNAL OF THE AMERICAN MEDICAL WOMEN'S ASSOCIATION that the data indicate relief of pain is causally related to the improved blood supply. Others have argued a major placebo effect. (Occasionally patients report less pain even when the bypass grafts are themselves completely blocked.) Another proposed explanation is that minor heart attacks during surgery and recovery destroy the pain-producing area. Whatever the mechanisms, most cardiologists and surgeons agree that when pain is not adequately controlled by medication, surgery is often valuable.

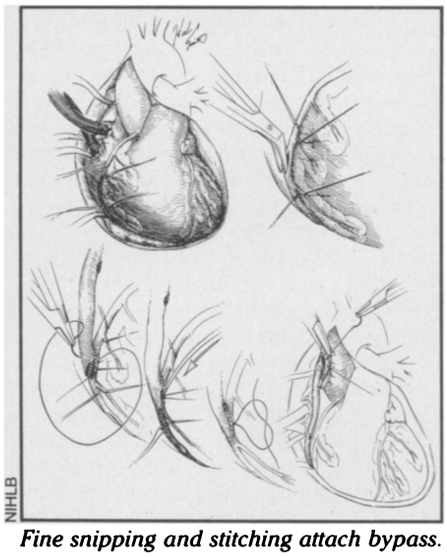
If the goal of bypass surgery is to increase the average lifespan of patients with coronary disease, then there are two cases of general agreement. No study has shown increased longevity after surgery of persons with only one vessel (excluding the left main artery) blocked. And in several studies patients with blockage of the left main artery have higher rates of survival after surgery, at least over the first three years, than with just medical treatment.

The sharpest clash comes over surgery for patients with two- and three-vessel disease who are not in intractable pain. As surgical procedures have improved in the last few years, the operation has become much less risky, and surgeons have become more aggressive in choice of surgical patients. W. Dudley Johnson of the Wisconsin Medical College in Milwaukee told a symposium celebrating the tenth anniversary of coronary bypass that of



NIHLB

Healthy coronary artery (from a 100-year-old woman) has wide passageway (top). Fatty deposits partially block the artery of another patient (bottom).



NIHLB

Fine snipping and stitching attach bypass.

1,000 angiograms he recently studied at Mount Sinai Hospital, he found only six patients unsuitable for surgery.

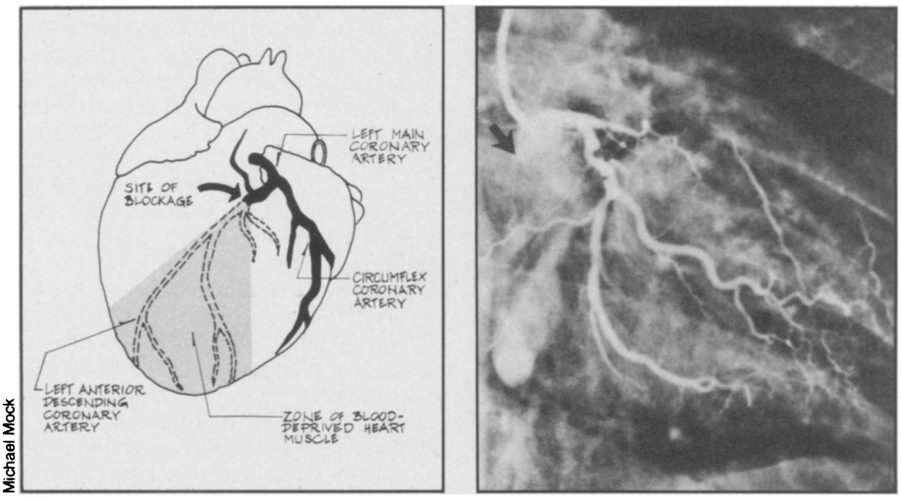
Some physicians even advocate "prophylactic" surgery in patients whose angiograms reveal blockages, though the patient has experienced no attack or chest pain. Another founder of bypass technique, Rene G. Favaloro of the Guemes Foundation in Buenos Aires, reports he has operated on patients who came to consultation because of an "ominous" family history. Johnson also reports surgery on asymptomatic patients with bad family histories, or where heart disease was discovered on a routine physical examination. "We continue to feel that coronary anatomy, independent of symptoms, should be a major factor in the selection of patients for surgery," he says.

The controversy over how wide a group of patients benefit from surgery involves several types of studies. The first comparisons were simply between the experience of patients receiving the new operation and the accumulated "natural history" of patients on older methods of treatment. McIntosh and Garcia point out that such studies may be of little value because the death rate from heart disease, although it is still this country's biggest killer, has been declining since 1963. Therefore, the natural history of the disease in the 1960s may have been significantly different than it is now.

Much of the available data on coronary artery bypass operations compares patients treated surgically at one hospital with patients treated medically at another. Such studies involving about 1,500 patients at Cleveland Clinic, Peter Bent Brigham Hospital in Boston and Stanford University suggest survival is improved in surgically treated patients compared to medically treated patients with the same number of affected vessels. A problem with such studies is that the patients in the two groups may not have exactly the same characteristics in factors that influence their survival. A Duke University group went so far as to use a computer to match 402 medically treated patients to 379 surgically treated patients according to 89 different variables of patient history, physical condition, laboratory results and prescribed therapy. When data of all the patients were analyzed together, the researchers found no difference in survival between medically and sugically treated patients, during the first two years. When patients were grouped into 12 groups by characteristics, a significantly improved survival was noted in one group with triple vessel disease.

A more convincing conclusion should result from "prospective" randomized studies. In that procedure, patients being considered for surgery are randomly assigned to the surgical or medical treatments. Then the researchers must wait years to compare the groups' survivals. Such a procedure would rule out the objection that healthier patients will be selected for surgery. A problem with setting up such experiments is that patients frequently desire surgery and will seek surgeons willing to operate. McIntosh and Garcia point out that about 400,000 patients have received coronary bypass operations, but only 1,300 have been reported who have been included in carefully controlled, randomized studies.

The results of the first prospective randomized study were reported in the Sept. 22, 1977 NEW ENGLAND JOURNAL OF MEDICINE. In the first three years after surgery no difference was detected in mortality rates between 596 surgical and medical patients with double and triple vessel disease in 12 Veterans Administration hospitals. After three years, 87 percent of the medical group and 88 percent of the surgical group were alive. (A more recent report of four-year survival rates gave a similar result. The Dec. 17, 1977 LANCET reported survival of 84 percent of



Michael Mock

Blockage at arrow interrupts blood flow. Angiogram (right) of a similar occlusion.

the surgical and 79 percent of the medical group — not a significant difference.)

A storm of protest followed. The response was so great that the journal devoted an entire section to letters on that report. The major objections to the Veterans Administration study were the choice of patients, the high mortality rates and the low number of grafts that successfully remained open.

Michael DeBakey of Baylor College of Medicine told SCIENCE NEWS, "I see no reason to feel that the VA study will have any effect whatsoever. We've passed that stage in patient selection. It was so highly restrictive, those are not the same people we are operating on now." The study excluded persons with a number of heart conditions and recent heart attacks. It included patients with lesions blocking the vessel only 50 percent, while many hospitals require a 75 percent reduction in vessel diameter for a "critical" lesion.

"The reported early surgical mortality of 5.6 percent in the Veterans Administration study is remarkably high .... Our experience [and the reported results of others] suggests that patients selected by these criteria, even at the time of this study, should have a surgical risk of 1 percent or less," wrote a group from Peter Bent Brigham Hospital. "It may be assumed that patients operated upon with such a high initial mortality and with a less than optimal number of grafts [1.9] may be expected to have higher than usual late attrition as well."

Rowe says "The VA study is a lousy study. They didn't revascularize enough." Rowe also says that an unacceptably high percentage of patients had heart attacks during the course of surgery. A group from Baylor College wrote to NEW ENGLAND JOURNAL OF MEDICINE to say a follow-up of 1,108 consecutive surgical patients in Houston revealed an operative mortality rate of 3.5 percent and a five-year survival of 90.0. Although they had no medically treated group to compare, they say the survival approaches that of a normal population of identical age and sex distribution. The Texas physicians report 87 percent of their bypasses remained open, while only 69 percent of the VA bypasses stayed unblocked. "We believe that this depressed graft patency rate is the principal reason why such poor surgical rates were obtained." Rowe says, "Passing is no good in a football game if the ball is intercepted."

There may even be dissension within the VA study. Physicians at Hines VA hospital near Chicago, which treated 139 of the patients, are reported to claim their surgical patients show significantly higher survival rates at three and five years than do patients treated just with drugs. VA cardiologists are currently re-evaluating and reviewing the Chicago data.

Eugene Braunwald of Harvard Medical School responded to the NEW ENGLAND JOURNAL OF MEDICINE letters. "Granted that the operative results (mortality, graft number and patency) in the best surgical centers today are superior to those obtained in the Veterans Administration trial several years ago, I maintain that these outstanding centers are less representative of the institutions in which 70,000 United States patients are operated upon each year than are the Veterans Administration hospitals that participated in the trial."

Nevertheless, it would be useful to settle whether the most skillful bypass surgery is valuable for patients with coronary artery disease. A National Institute of Heart, Lung and Blood study just underway at 18 leading surgical centers across the country should avoid the pitfalls of the VA study.

The Coronary Artery Surgery Study (CASS) begins with a computer categorization of all patients examined with angiograms. That in itself is expected to provide valuable information about coronary artery disease. For example, of the people examined by angiography, more than a quarter had insignificant blockage, while almost half had significant multivessel disease. The data collection also has shown that about 8 percent of the patients with the disease have blockage of the left main coronary artery.

Next, patients with double or triple vessel disease (but not left main artery disease) are randomly assigned to medical or surgical groups. The patients are told that no one yet knows the value of the operation. "We really don't know, otherwise we couldn't do the study," says Michael Mock of NIHLB. So far, more than 16,000 patients have been listed in the registry and 500 have been randomized. The goal is to have 25,000 registered and 900 patients randomized by June 1979. The NIHLB scientists plan to follow the patients for five years. "It's important not to release information too soon," Mock says. "Curves can change."

Medical and surgical treatments should not assume adversary roles, DeBakey insists. The problem is deciding which is most appropriate to each patient. Mock sees a parallel between the situation in heart surgery today and in the early days of antibiotics. "At first they used penicillin for everything, even colds," Mock says. "The improper use didn't mean it was not a lifesaving drug for severe infections. Penicillin was not the answer for all infections, and bypass surgery is not going to be the answer for all coronary disease. It may be wonderful for one person, but giving everyone a bypass isn't going to solve all the problems." The final solution, he says, must answer the questions of what causes the disease and what triggers heart attacks.

For the time being, Mock considers concrete indicators for surgery to be left main artery disease, pain not controlled by maximal medical therapy and patient dissatisfaction with quality of life. As far as the clinical judgement of aggressive surgeons, Mock says, "They may think in their hearts they're really doing the best thing, but it's not proven." □