

## Is Heart Surgery Worth It?

**Physicians are questioning whether bypasses and angioplasties necessarily prolong patients' lives**

You start breathing hard after climbing stairs, and your chest hurts. You go to your doctor. Scans reveal that arteries feeding your heart are severely narrowed. Your doctor sends you to the hospital for coronary bypass surgery or angioplasty to restore the blood flow to your heart. Despite the trauma of surgery, you're glad the blockage was caught in time, saving you from a potentially fatal heart attack.

There's just one problem with this happy tale of modern medicine: More and more doctors are questioning whether such heart procedures are actually extending patients' lives. One of them, Dr. Nortin M. Hadler, professor of medicine at the University of North Carolina at Chapel Hill and author of *The Last Well Person*, is urging the U.S. medical Establishment to rethink its most basic precepts of cardiovascular care. Bypass surgery in particular, he says, "should have been relegated to the archives 15 years ago."

That is an extreme view that is disputed by cardiac surgeons. "The reason thousands and thousands of bypass surgeries have been done is that [the procedure] is successful," says Dr. Timothy J. Gardner, co-editor of *Operative Cardiac Surgery* and a cardiothoracic surgeon at Christiana Care Health System in Wilmington, Del.

Nevertheless, the data from clinical trials are clear: Except in a minority of patients with severe disease, bypass operations don't prolong life or prevent future heart attacks. Nor does angioplasty, in which narrowed vessels are expanded and then, typically, propped open with metal tubes called stents. "People often believe that having these procedures fixes the problem, as if a plumber came in and fixed the plumbing with a new piece of pipe," explains Dr. L. David Hillis, professor of cardiology at the University of Texas Southwestern Medical School. "But it fundamentally doesn't fix the problem."

With doctors doing about 400,000 bypass surgeries and 1 million angioplasties a year -- part of a heart-surgery industry worth an estimated \$100 billion a year -- the question of whether these operations are overused has enormous medical and economic implications. "It is one of the major issues in cardiology right now," says Dr. David Waters, chief of cardiology at the University of California at San Francisco.

It is also part of a far broader problem -- what some health-care experts call the medicalization of life. "None of us will live long without headache, backache, heartache, heartburn, diarrhea, constipation, sadness, malaise, or other symptoms of some kind," argues Hadler. Yet under relentless bombardment by messages from the pharmaceutical and health-care industries, Americans increasingly believe that these symptoms -- and many others -- are conditions that can and should be cured. "We have an image of ourselves as invincible and powerful and able to overcome all odds," Hadler says. "And the lay press is too quick to talk about the latest widget and gizmo without asking what it is and does it work."

**HIGHER COST, BIGGER RISK**

Indeed, there is compelling evidence that more health care and more aggressive treatment across the complete spectrum of illnesses is not necessarily better. When Dr. Elliott S. Fisher, professor of medicine at Dartmouth Medical School, first looked at regional differences in health-care spending in the U.S., he assumed that people in areas with lower expenditures would have worse health than people in regions where spending was 1 1/2 to 2 times as high because they were failing to receive needed care. It turned out that the opposite was true. "Patients have a substantial increased risk of death if cared for in the high-cost systems," he says. Why? For one thing, additional doctor visits and testing often lead to unnecessary procedures and hospitalizations, which carry risks. **"My data suggest that we are wasting 30% of health-care spending on stuff with no benefit and perhaps causing harm," says Fisher.**

International comparisons support his reasoning. The U.S. spends 2 1/2 times as much as any other country per person on health care, but that doesn't translate into better outcomes, according to studies that compare such indicators as fatality rates after a heart attack and length of survival after a kidney transplant. That suggests that "the investment in health care in the U.S. is just not paying off," says Gerard Anderson, director of the Center for Hospital Finance & Management at Johns Hopkins Bloomberg School of Public Health and co-author of a 2004 study that looked at 21 different health-quality indicators in five nations.

Similar comparisons can help pinpoint dubious treatments. The classic case: tonsillectomy. In the early 1970s, Dr. John E. Wennberg, now director of the Center for Evaluative Clinical Sciences at Dartmouth Medical School, showed that some hospitals removed tonsils 10 times as often as others. But the children in areas with low rates weren't worse off, so the operation fell out of favor. More recently, Dr. James N. Weinstein, chair of orthopedic surgery at Dartmouth-Hitchcock Medical Center, found that people with back pain are up to 20 times as likely to have back surgery in some parts of the country as in others. Yet it's not clear that they do better as a result. Weinstein is comparing the outcomes in patients who get different treatments, from rest and physical therapy to spinal fusion. Meanwhile, he says, "billions of dollars are being spent without good information."

This is of obvious concern to those who pay for health care, from the government to private insurers, which are struggling to better balance costs and benefits. And nowhere are the financial and health stakes higher than in the area of cardiac surgery. U.S. patients and insurers will spend \$3.4 billion this year on drug-coated stents from suppliers Boston Scientific Corp. ([BSX](#)) and Johnson & Johnson ([JNJ](#)), according to Citigroup. At many hospitals, cardiac units have become major profit centers. "We've shown that it is a lucrative area for hospitals," says Paul B. Ginsburg, president of the Center for Studying Health System Change. But are heart procedures always the best path for patients who currently get them?

The answer seems to be no. As Hadler describes in his book, data from bypass-surgery clinical trials in the late 1970s show that the procedure extends life or prevents heart attacks only in a small percentage of patients -- those with severe disease. More recent trials with angioplasty show it reduces deaths mainly just in emergencies. "For people in the throes of heart attacks, opening the artery definitely prolongs life," says UCSF's Waters. Not so for patients with stable chronic disease. "The overwhelming number of heart procedures done these days do not affect patients' life span at all," says Hillis.

**The latest thinking on heart attacks may explain why not. In the traditional view, the slow accumulation of plaque inside arteries gradually narrows the vessels. Reduced blood flow**

**causes chest pain, or angina. Eventually the arteries are blocked, bringing on heart attacks. Newer evidence, however, pins the blame not on this gradual narrowing but on unstable plaque that breaks off and causes clots. The clots are what obstruct the arteries, causing the heart attacks -- which is why so many such events are unexpected and why "there is no evidence that opening chronically narrowed arteries reduces the risk of heart attack," says Waters.**

## **DIET AND LIFESTYLE**

A better way to lower heart-attack risk is to fight the unstable plaque with aggressive cholesterol-reducing drug therapy, diet, and lifestyle changes, many cardiac physicians say. That can be a tough sell to patients who want a quick fix, says Hillis. "Medical therapy is just not as sexy as doing a procedure," he explains. "The assumption our society makes is that the more aggressive your medical care is, the better it is. It's not true. But if I explain to a patient why he doesn't need surgery, 9 times out of 10 he will go across town and find someone who will do the procedure."

The surgeries do relieve angina symptoms -- and for some doctors that's a slam dunk. Emory University cardiologist Dr. Robert A. Guyton, co-chair of the American College of Cardiology and the American Heart Assn. committee that wrote the current bypass-surgery guidelines, points to patients disabled by pain and shortness of breath who, a month after bypass surgery, "are walking around as healthy as you or I," he says. "To say the whole operation ought to be scrapped is nuts." Similarly, angioplasty eases the often crippling pain of angina. "There is quite a lot of good evidence for symptom relief," says Dr. Robert Henderson, a cardiologist at Nottingham City Hospital in Britain and co-investigator for a key angioplasty clinical trial.

Critics such as Hadler, on the other hand, emphasize the risks. Not only is there a 1% to 2% chance of dying during a bypass operation, he explains, there is a high risk of complications and a 40% chance of cognitive deficits. The healthy, active post-surgery patient is an "urban legend," he says. "An alarming number never return to the workforce or describe themselves as well again."

Recent studies even raise questions about whether surgery causes the symptom relief. In June, Harvard Medical School associate professor of medicine Dr. Roger J. Laham reported on follow-up results of a randomized trial looking at laser surgery to improve blood flow. Patients who got the surgery had significantly less pain and improved heart function. But so did patients who had a sham operation -- the equivalent of a placebo. After 30 months the placebo effect was still there. Scans and other tests showed physiological gains in blood flow among only those who thought they had been operated on. A similar large placebo effect might explain "most of the benefits that we've seen so far with balloon angioplasty and bypass surgery," Laham says.

There are also fresh concerns about the safety of drug-coated stents, now widely used in angioplasty. When doctors first tried to open clogged arteries with a balloon, they found that arteries soon closed again. So they began inserting metal mesh stents to hold them open. When arteries continued to clog up again, companies devised stents impregnated with drugs that slow the growth of cells, reducing chances that patients would have to have their arteries opened again.

First approved in April, 2003, drug-coated stents account for 88% of the stents used in the U.S. But when pathologist Dr. Renu Virmani, medical director of CVPPath, a research service of the International Registry of Pathology, examined the hearts or heart vessels of 39 patients who died after getting the new stents, she found clots in 11 cases that developed more than 30 days after the

procedure. The sample is small, and it's not clear that the clots caused the deaths. But it's a big jump from her experience with patients who died after getting bare-metal stents. Just 12.5% of them had late-developing clots.

What worries some doctors is that people getting the new stents might have a higher risk of clots, which then could cause heart attacks more than a month after the procedure. "Out of 100 patients who get a drug-coated stent vs. a bare-metal stent, maybe 10 will avoid a repeat procedure," says Dr. Eric J. Topol, chief of cardiology at the Cleveland Clinic Foundation. "But how many will wind up with a heart attack or death? Maybe one in 1,000? We just don't have that nailed down yet." Drug-coated stentmakers Boston Scientific and Johnson & Johnson say their clinical trials show no such increased risk of late-developing clots.

Cardiac surgeons readily admit there are big unanswered questions. "We can handle the criticisms, and we should be accountable," says cardiothoracic surgeon Gardner. "But there is plenty of hard work going on to try to determine the appropriate patients for whom such treatments are necessary." There are also large clinical trials under way comparing surgery with cholesterol-reducing drugs and other medical treatment, which will provide better answers. If the trials show no benefit to surgery compared to medicine, "it will be a serious challenge to the coronary-intervention industry," says Dr. Robert H. Jones, distinguished professor of cardiothoracic surgery at Duke University Medical Center. His prediction? "I'm a surgeon, so I think surgery will hold up."

The answers still may not be definitive, however, because medicine continues to advance. "Every time these studies come out and show that revascularization [improving blood flow] doesn't do much, cardiologists say: 'Well, that study was started four years ago, and now we have shinier stents, and the results are better,'" notes UCSF's Waters. "But medical therapy [with drugs] is getting much, much better, too." Harvard's Laham suggests that as many as 400,000 of the angioplasties done in the U.S. each year may be medically unwarranted. "I'm sure we are way overtreating our patients," he says.

Some scientists argue that the rational solution is to let patients decide for themselves. But that requires providing detailed information about the risks and benefits of medical procedures, such as coronary surgery -- including the unknowns. In trials where one group gets the information and the other group receives no special attention, the well-informed patients opt for more invasive, aggressive approaches 23% less often, on average, than the other group. Without this full information, "patients typically don't understand that they have options, and even if they do, they often wildly exaggerate the benefits of surgery and wildly minimize the chances of harm," says Annette M. Cormier O'Connor, clinical epidemiologist at Ottawa Health Research Institute and a leader in this field of so-called decision aids.

It's a model approach for medicine in general. As Hadler argues, the exaggeration regarding benefits goes far beyond heart surgery. Too many common conditions are viewed as diseases needing treatment, and too many treatments of uncertain benefit are used too often. "What Hadler does is question the soundness of that thinking in a very profound way," says Dr. Glenn D. Pomerantz, senior vice-president for global innovation at Cigna ([CI](#)). Hadler hopes that enlightening people about the limitations of medicine will help them worry less and stay well longer. It also could help cure an ailing health-care system, making it more rational. In the end, few doctors will object to the basic prescription: Avoid drastic procedures that probably won't help and might actually do harm.