

Shocking Survival

Implantable devices jolt the heart back to life



By KATHY A. FACKELMANN

A middle-aged California woman who had survived a previous episode of cardiac arrest had agreed to serve as a guinea pig of sorts.

Heart surgeon Levi Watkins Jr. remembers the February 1980 operation this way: Surgical team members assembled in Operating Room 12 of the Johns Hopkins Hospital in Baltimore. With the patient anesthetized, they inserted a battery-operated device — about the size of a pack of playing cards — under the skin just above her navel. They also made an incision in the chest to expose her heart. Gingerly they attached electrodes to the heart's upper right chamber and lower tip.

That was the easy part.

Next, the surgeons stopped the heart by shocking it with a jolt of electricity. Then, after what Watkins recalls as the longest 30 seconds of his life, the implanted device fired another electrical shock and the heart resumed its life-giving rhythm.

It was a moment of elation for everyone involved, but a particularly broad smile flashed across the face of cardiologist Michel Mirowski, who had invented the world's first implantable defibrillator after a colleague suddenly dropped dead. Mirowski had turned his grief into a quest to help prevent cardiac arrest, a disorder that by its very nature strikes without warning, often killing seemingly healthy individuals in the prime of life.

Any of several underlying heart ailments can lead to cardiac arrest, which occurs when an electrical disturbance in the heart sparks a rapid or chaotic heartbeat. Without immediate medical attention, this runaway arrhythmia can kill within minutes.

"We call it sudden cardiac death because ordinarily these people are doing alright, and the next moment they're on the ground," says Watkins. "It's very quick and very catastrophic."

More than a decade has passed since Watkins, Mirowski and their colleagues undertook that

five-hour landmark operation. Today, hundreds of medical centers nationwide offer the device to people who risk developing a potentially deadly arrhythmia. At the American Heart Association's 64th scientific sessions, held last month in Anaheim, Calif., a California surgical team presented new data on the long-term survival of people fitted with implantable defibrillators, and New York researchers described their use of the device to keep heart patients alive during the lengthy wait for a donor heart.

Although often confused with a heart attack, cardiac arrest means simply that the heart has stopped beating after developing ventricular tachycardia or ventricular fibrillation, two types of arrhythmias. In ventricular tachycardia, the heart's lower pumping chambers (ventricles) beat too rapidly; in ventricular fibrillation, they quiver chaotically.

People who have a heart attack — in which a clot, spasm or a fatty deposit blocks the heart's blood supply — can suffer cardiac arrest at the time of the attack or later, when damage to the heart muscle disrupts the organ's electrical circuitry and leads to a ventricular arrhythmia. Cardiomyopathy — heart inflammation that can result from a variety of causes, including viral infections — also places the heart at risk of developing a dangerous arrhythmia.

Sudden cardiac death kills more than 300,000 people each year in the United States, notes Arthur J. Moss of the University of Rochester (N.Y.) Medical Center. He and a coalition of cardiologists contend that sudden cardiac death has reached "epidemic" levels in the United States. Implantable defibrillators, they said at a press conference during the heart meeting, could help prevent many of those deaths.

In the largest and most definitive study yet of people fitted with implantable defibrillators, researchers at Stanford University Medical School have found that nearly 60 percent of these patients survived at least 10 years with

the device — an overall survival rate that Watkins terms "extraordinary."

The Stanford team, led by cardiologist Roger A. Winkle, recruited 650 people who had experienced a life-threatening arrhythmia, about 80 percent of them men. In most cases, the arrhythmia episode had required emergency medical help, including an external defibrillator. This machine, the size of a personal computer or larger, delivers a much stronger surge of electricity than the implantable device (200 to 400 joules, compared with about 30). Technicians place two paddles on the skin, one on each side of the heart. If all goes well, the ensuing jolt — which can jerk the entire body — shocks the quivering heart into resuming a regular beat.

Most people who live through this trauma readily consent to the open-heart surgery required to implant a small defibrillator, Winkle says. All 650 recruits in his study underwent surgery to implant the device, beginning in February 1981.

Once implanted, the defibrillator continually monitors the patient's heartbeat. If the rhythm suddenly goes into overdrive, the device fires off a small electrical shock that travels along the wire leads to the heart. The lithium batteries used in the early implants lasted about three years; today's batteries last at least five years. When a battery runs low, surgeons replace the old defibrillator with a new one, reattaching the leads to the heart in a fairly simple operation, Winkle says.

Most of the study participants also received standard drug treatment to control erratic heartbeats. However, doctors know that such drugs don't completely erase the risk of a lethal arrhythmia. Indeed, during the 10-year Stanford study, most patients experienced episodes in which the defibrillator fired, Winkle says.

Patients describe varying reactions to the internal jolt, he adds. Some don't feel anything, others say the sensation reminds them of a hiccup, and still others report that the shock knocked them to the ground.

As of last month's meeting, only 18 of the 650 participants had died of cardiac

arrest. Without the device, the team would have expected about 144 such deaths, Winkle says.

The per-year death rate from cardiac arrest in this group—only 1 percent—was astonishingly low, he adds. Without the device, an estimated 20 to 40 percent of these patients would die from cardiac arrest each year, Winkle says.

The per-year death rate from unrelated causes, including cancer, stroke, infections and other diseases, averaged about 3 percent in these patients. "This device does absolutely nothing to prevent death from other causes," Winkle notes. "When you figure that the average age at implant is 61 years, to have almost 60 percent alive 10 years later—when the patients are in bad shape at the start—isn't bad."

Winkle's results fit with data culled by Watkins in 1989 from an eight-year study of people with implanted defibrillators. "At the 10-year point, the [implantable defibrillator] continues to be a pretty reliable device," Watkins says.

In a slightly different use of the defibrillator, a New York team hopes to learn whether the device can help stave off cardiac arrest among patients awaiting a heart transplant.

Because of the severe shortage of donor hearts, most transplant candidates face a waiting period of more than a year, says Valluvan Jeevanandam, a cardiac surgeon at Columbia-Presbyterian Medical Center in New York City. At Columbia-Presbyterian, the wait averages 16 months, and 30 to 40 percent of the candidates die before a suitable heart becomes available. Most of those deaths result from ventricular fibrillation and cardiac arrest, Jeevanandam says.

So he and his colleagues have turned to the implantable defibrillator.

People waiting for a new heart typically suffer from congestive heart failure, a long-term inability of the heart to pump effectively, sometimes due to underlying disease such as cardiomyopathy and sometimes due to the damage caused by numerous heart attacks.

Ordinarily, transplant candidates who risk developing a lethal arrhythmia remain in the hospital, with ready access to an external defibrillator. In some cases, these high-risk patients live in the hospital for months. With the implantable defibrillator, Jeevanandam reasoned, doctors could send patients home, knowing that if a risky rhythm developed, the device would likely restore a regular beat.

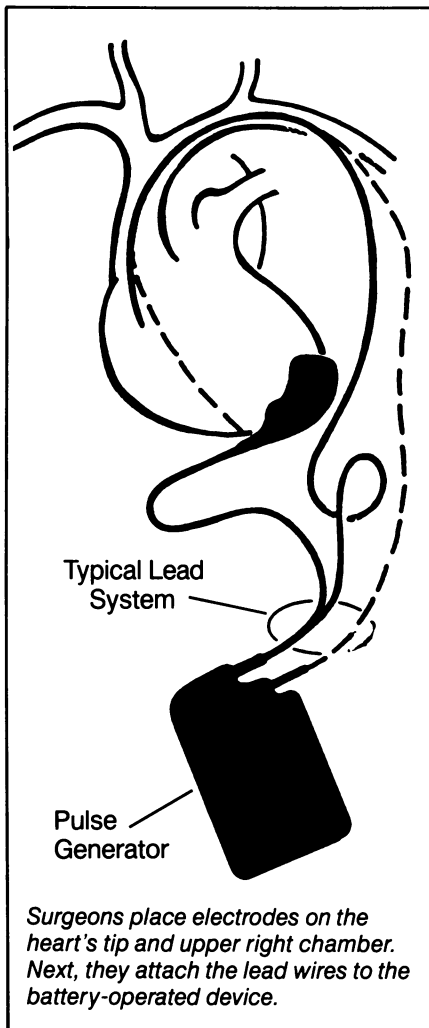
To test that idea, he and his co-workers selected 16 men who were waiting for a heart transplant after experiencing a life-threatening arrhythmia. All 16 volunteered to receive the implantable device.

After waiting an average of 230 days, 12 of the 16 have gone on to receive a new heart. The other four remained on the transplant list, Jeevanandam notes. So

far, he says, the device has fired an average of six times in each patient.

"The fact that almost all of them fired their device means that those patients would have died without the device," Jeevanandam says.

Winkle expresses concerns about this use of the implantable defibrillator, citing the high cost of the procedure. Nonetheless, he says, "the device will certainly save some lives as a bridge to transplantation."



operation, the hospital bill runs about \$50,000, Winkle says. Although surgeons try to keep side effects to a minimum, patients do run a risk of infection, he notes. And it often takes weeks to recover from the trauma of open-heart surgery.

But Winkle's team and others have already moved on to the next generation of implantable defibrillators, which do not require open-heart surgery. Instead of relying on electrodes attached to the outside of the heart, these devices feature two small coils that are snaked through the blood vessels to the heart. Once inside the heart, the coils can deliver the same life-giving jolt of electricity as the old system.

Johns Hopkins cardiologist Thomas Guarnieri, in collaboration with Winkle and a number of other investigators, has completed a one-year study of 215 people who received implantable defibrillators. Guarnieri says 70 percent of the patients got the new system and it worked well for them.

Much work remains to identify ideal candidates for the gentler method, Guarnieri adds. But he believes the new devices may be in widespread use by the turn of the century.

Also on the horizon: implantable defibrillators that contain a pacemaker. Most people who need a pacemaker suffer from abnormally slow heartbeats, Watkins notes. However, researchers believe that a combined pacemaker-defibrillator may benefit people who risk cardiac arrest due to abnormally fast heartbeats. To interrupt that risky, rapid rhythm, the pacemaker would fire electrical signals to speed up the heart and then pace it back to a normal rhythm. If that strategy failed, the defibrillator would kick in, delivering its higher-powered jolt, Watkins explains.

Hear researcher Thomas J. Bigger Jr. remembers one middle-aged man—the president of a toy factory, with a wife and young kids—who survived a cardiac arrest, got an implantable defibrillator and then went for years without experiencing another ventricular fibrillation. During the sixth year after implantation, the device fired for the first time.

"It saved his life," says Bigger, of the Columbia University College of Physicians and Surgeons in New York City.

His story demonstrates that cardiac arrest can, in many cases, be prevented. In the past, physicians viewed cardiac arrest as a sure sign that a heart had become too sick to survive. Now they believe that the heart may remain viable despite these risky episodes. With an implantable defibrillator, patients may be able to prepare for that threat.

"Once you realize that... then the pressure on you to find these people and do something becomes intense," Bigger says. "I think about it every day." □

Watkins envisions a much broader market for the device in the not-so-distant future, especially if scientists can find ways to identify seemingly healthy people who face a high risk of dangerous arrhythmias. For now, he says, physicians do not consider implanting a defibrillator unless a patient has already experienced a potentially lethal arrhythmia and/or a cardiac resuscitation. And many doctors and patients hesitate to elect a risky and expensive operation that involves cracking the chest, especially for people who show no outward signs of ill health.

The implantable device currently costs about \$17,000; with a typical open-heart

Cardiac Pacemakers, Inc.