

Hotwire my heart

Growing numbers of people are being implanted with electronic devices that can automatically restart a failing heart. But have the risks and benefits been adequately assessed? Duncan Graham-Rowe investigates.

Cardiologist Michael Sweeney has vivid memories of the day he inadvertently set off an explosion inside a 79-year-old man's chest. It was 2001, and the patient had come into the Brigham and Women's Hospital in Boston for a routine check on his implantable cardioverter defibrillator, or ICD. Inserted under the pectoral muscles, an ICD can deliver a life-saving electric shock to a failing heart.

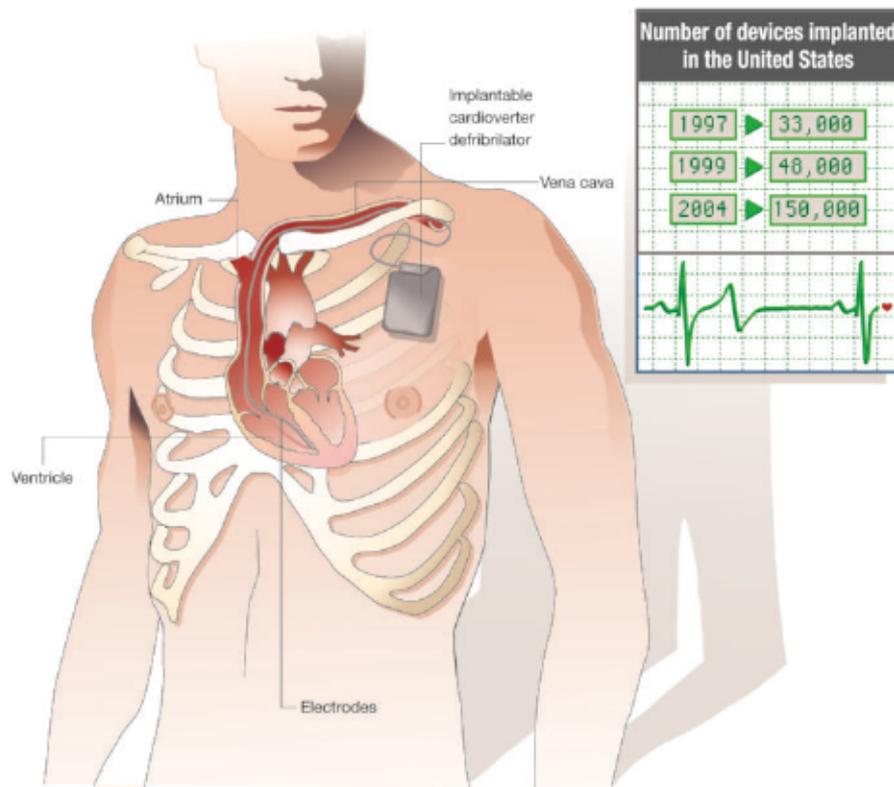
But when Sweeney attempted to set off a test shock from the device, there was a blue flash from the patient's chest and a loud popping sound. A short circuit in his ICD had ruptured its titanium casing¹. If the man hadn't been in hospital, says Sweeney, he almost certainly would have died.

To be fair, this same device, the man's fourth, had previously restarted his failing heart several times. But the incident illustrates that having one of these potentially life-saving implants is not risk-free. Although such catastrophic electrical failures are mercifully rare, the surgery required to install, maintain and replace ICDs exposes patients to the danger of infection. And with the devices becoming increasingly popular, experts are now beginning to wonder whether — for some of the patients now receiving them — the risks might outweigh the benefits.

"As defibrillators are being implanted in a larger number of people, the probability that each device will be required to save a person's life will go down," says Charles Swerdlow, a cardiologist at the Cedars-Sinai Medical Center in Los Angeles. Indeed, if your heart never actually fails, you will get all of the risks associated with having an ICD, and none of the benefits — apart, perhaps, from the peace of mind of knowing that the device is there, should you ever suffer a cardiac arrest.

Life saver

ICDs are extremely effective for people at high risk of heart failure. They apply shocks to the heart through conducting leads that are anchored within one of its chambers (see diagram, above right). They can either act as pacemakers, providing small pulses to maintain the heart's rhythm, or deliver much more powerful jolts. The latter can resynchronize the contractions of the heart's muscle if it has entered a chaotic or dangerously fast rhythm, or restart the heart if it stops beating.



Until recently, the only people who qualified for an ICD either suffered from potentially lethal abnormal heart rhythms, or had survived a previous cardiac arrest. But in recent years, official guidelines have extended their use to include many patients who are deemed likely to suffer heart failure. Over the past seven years, the number of people receiving ICDs in the United States has increased nearly fivefold.

Overall, this trend is thought to be saving lives. Indeed, in the largest ever ICD trial, published in January and involving more than 2,500 patients, the devices reduced mortality by 23% in people with 'moderate' heart failure, compared with those who were treated with drugs alone². On the basis of these results, the US Centers for Medicare and Medicaid Services expanded its criteria for treatment with an ICD. According to the leading ICD manufacturer, Medtronic of Minneapolis, 1.6 million Americans are now eligible for the devices. That's about five times the number of patients who have so far received one.

But some experts are sceptical of the need

to give implants to so many patients. Most of the trials of ICDs, they note, are sponsored by the manufacturers of the devices — which have a vested interest in seeing them used more widely. "I think inherently there is a conflict of interest," says Sweeney. "The companies are looking for a return on their investment."

Risk assessment

In particular, some cardiologists argue that more research should be done to distinguish between the patients at the highest risk of heart failure, and those who are unlikely ever to need a shock from an ICD. In the trial published earlier this year, for instance, only one in three of the devices delivered a shock over the five-year study². "Probably the large majority of those with ICDs will never have therapy," says Adrian Almquist, a cardiologist at the Minneapolis Heart Institute.

Some cardiologists argue that a series of simple, non-invasive tests could be used to identify the patients at highest risk of cardiac arrest. Certain features of an electro-

cardiogram (ECG), for instance, may give a good indication of such risks.

In the trial published in January this year, too few patients had been subjected to these tests for definitive conclusions to be drawn². But in unpublished preliminary research, Morrison Hodges, also at the Minneapolis Heart Institute, has reanalysed ECG data from previous trials and found that they

could give an improved risk assessment for individual patients. Hodges now wants to conduct a multicentre trial in which thousands of ICD patients would be monitored over several years, in order to refine his predictive model. He approached Medtronic to see if it wanted to get involved, but the company wasn't interested. That's hardly surprising, says Hodges: "These tests are better at

inappropriately or to fail to be shocked when they need to be. The explosion that nearly killed Sweeney's 79-year-old patient was an extreme case, admittedly — the coiled lead of his device had worn through its insulation. But cardiologists fear that similar incidents may become more common in future. "The problem is that devices are getting smaller and smaller," says Almquist. This will make it harder to separate and adequately insulate the high-voltage circuits in them, he argues.

One worrying sign came in February, when Medtronic issued a warning that some of its Marquis model ICDs could develop a short circuit leading to the rapid discharge of the battery. The problem, a result of design changes made in miniaturization, would cause the device to emit an audible 'low battery' tone, or completely fail to work.

"We changed the manufacturing process and that problem does not occur any more," says Marshall Stanton, the company's vice-president and medical director, cardiac rhythm management. Only nine such failures have been reported, he adds, and the company's tests suggest that no more than 1.5% of 87,000 implanted Marquis devices are prone to the problem.

Hidden failure

But the true incidence of ICD failure remains unknown. A 2001 attempt to evaluate the problem concluded that mechanisms for reporting are inadequate³. In the United States and many other countries, there is no legal obligation for doctors to report a device failure and no central independent database to collate this information, says Almquist, who co-authored the study. John Camm, a cardiologist at St George's Hospital in London, suspects that only about one in ten ICD failures are reported.

"It is quite likely that there are dead patients whose devices failed," adds Sweeney. Under a different doctor, his 79-year-old patient could well have joined their number — Sweeney's clinic is unusual in that it runs checks in which patients are sedated and their devices are test-fired. "You have to turn over stones to find worms," he says.

Given the uncertainties, Sweeney and other experts argue that it's time to start turning over stones in a more systematic manner. If current trends continue, says Sweeney, we may get to the point where guidelines recommend ICDs for almost everyone with a possible risk of cardiac arrest. "And that is a very unsatisfactory position," he notes.

Duncan Graham-Rowe is a freelance journalist in Brighton, UK. He has a potentially lethal heart arrhythmia for which the only treatment is an ICD.

1. Sweeney, M. O. *J. Cardiovasc. Electrophysiol.* 12, 1422-1424 (2001).
2. Bardy, G. H. *et al. N. Engl. J. Med.* 352, 225-237 (2005).
3. Hanser, R. G. *et al. Pacing Clin. Electrophysiol.* 24, 1046-1054 (2001).

IMAGE UNAVAILABLE FOR COPYRIGHT REASONS

An implantable defibrillator will restart a failing heart, but do so many patients need one?

IMAGE UNAVAILABLE FOR COPYRIGHT REASONS

identifying patients who don't need a defibrillator than those who do."

On cost grounds alone, there are good reasons to think carefully about who should be implanted with an ICD. Each device costs about US\$40,000, and every ICD patient requires lifelong care. The devices typically have to be replaced every five years or so, and they must regularly be monitored

and serviced. Occasionally, parts such as the electrodes must be replaced. And each surgical intervention exposes the patient to the risk of infection. "This isn't like changing a part in your car," says Swerdlow.

And then there is the risk of electrical failures.

These can cause patients to receive a shock



Non-invasive techniques could help decide who gets an ICD.

S. CAMAZINE/ALAMY

BUSINESS WIRE PHOTO/NEW ECON

MEDTRONIC