

Implanted devices as effective in 'real world' as in clinical trial settings

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Implanted devices that treat cardiac dysfunction in heart failure patients are as successful in "real world" use as they are in controlled clinical trial settings, according to a large new study reported in *Circulation: Journal of the American Heart Association*.

In the study, researchers focused on three devices:

- Implantable cardioverter [defibrillator](#) (ICD) — shocks the heart to treat dangerously fast rhythms in its lower chambers, or ventricles, and can also treat sudden cardiac arrest;
- Cardiac resynchronization therapy (CRT) —coordinates pumping of the two ventricles and improves heart efficiency in [heart failure](#) patients;
- CRT-D — a defibrillator with a CRT device.

Researchers examined data on 185,778 ICD and CRT patients (average age 67). After one year, 92 percent of ICD recipients and 88 percent of CRT-D patients were alive. Survival rates after five years were 68 percent for ICD and 54 percent for CRT-D. Among 8,228 CRT-only patients, the survival rate was 82 percent at one year and 48 percent at five years.

"I'm very encouraged that survival after defibrillator implant is as good

as it is for as long as it is," said Leslie A. Saxon, M.D., co-author of the study.

The data complement previous results of [clinical trials](#) that evaluated ICDs for primary prevention of sudden death. Real world patients were expected to fare worse because they could also be using an ICD for secondary prevention (recurrent event), which puts them at higher risk.

The study also found that patients whose devices were subject to ongoing remote monitoring on a network were about half as likely to have died as were those receiving traditional in-clinic monitoring only, which typically occurs quarterly.

"There's a lot of good news here," said Saxon, chief of the division of cardiovascular medicine at the University of Southern California's Keck School of Medicine in Los Angeles. "We need to expand the capabilities of these networks; they are very promising for our patients."

Cardiologists decide whether to enroll patients in a remote monitoring network, which is available only for ICD and CRT-D devices and is free. Enrolled patients are mailed a communicator unit that connects to their telephone line and queries the implant daily about how it's functioning and whether cardiac events occurred. That data is delivered to a website the physician monitors.

The communicator can also help monitor other health indicators, dispatching data on factors such as fatigue, weight or blood pressure. Changes in weight and blood pressure can predict worsening status. Patients with CRT-Ds whose communicators regularly transmitted weight and [blood pressure](#) data had a lower risk of death than did other networked CRT-D patients.

Because the network gives a continuous view of patients' status — and

provides alerts when something is wrong — physicians can more effectively triage their patients and intervene immediately.

"It's highly likely the reason these patients did better is that they were receiving earlier diagnoses, and they were also empowered to take charge of their own health care more," Saxon said. "I don't think there's any reason not to put a patient on it."

The new study is part of ongoing research called the ALTITUDE project, involving physicians from across the United States who are learning how to optimize ICD, CRT and CRT-D devices.

"We're trying to use data from tens of thousands of patients to better individualize therapy and get the best outcomes out of it," Saxon said. "It's a new frontier of managing sick patients."

Patients who received a CRT-only device, and who as a group fared worse than the others, were older, with an average age of 76. Selection bias may help explain their lower survival rates, Saxon said. The patients received the CRT-only devices because they tended to be sicker and doctors focused on resynchronization to support the heart, with less attention to the possibility of arrhythmias.

"Maybe those patients died more because they didn't have a defibrillator and they succumbed to a malignant arrhythmia," she said.

Most patients given implantable heart devices in the last five years have received the defibrillator part of the device to prevent death from sudden cardiac arrest, Saxon said.

"Without defibrillators, 98 percent of patients (with a malignant arrhythmia) die because they require a shock right away," she said.

The implants can deliver that shock within about 15 seconds.

Provided by American Heart Association

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