

Defibrillators save lives, don't diminish quality of life

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Implantable cardioverter-defibrillators (ICDs) reduce the risk of death from sudden cardiac arrest (SCA) among patients with heart failure, and they do so without significantly altering a person's quality of life, say researchers from Duke University Medical Center.

The finding – from the longest and most comprehensive study to date of ICD use to prevent SCA – may go a long way toward easing physician and patient concerns about the side effects of the therapy.

"Basically, we wanted to find out if ICD therapy improves longevity but only at the cost of worse quality of life," says Dr. Daniel Mark, a cardiologist at Duke and the lead author of the study appearing in the September 4 issue of the *New England Journal of Medicine*.

The ICD used in the study was a relatively simple model implanted in the upper part of patients' chests on an outpatient basis. An ICD monitors the heartbeat for arrhythmia and delivers a jolt of electricity to restore normal rhythm if needed. Some patients describe the shocks as painful and unsettling, and earlier studies suggested that the mere anticipation of being shocked can cause significant anxiety.

Mark and colleagues prospectively studied 2521 patients enrolled from 1997 to 2001 in the Sudden Cardiac Death in Heart Failure Trial. All participants received state-of-the-art medical therapy for heart failure. In addition, one third of the patients were randomly assigned to receive an ICD, a second group was assigned to receive the anti-arrhythmia drug amiodarone and a third group took an amiodarone placebo.

Researchers interviewed each participant four times over a 30-month period to assess disease status, physical and social activity levels, psychological well-being and ability to perform

routine daily tasks.

While members of all groups had essentially the same scores on psychological well-being at the beginning of the study, patients with the ICDs actually had somewhat higher quality of life scores at 3 and 12 months, when compared to those in the other groups. Scores of other quality of life measures also improved over a short term among ICD users, but all differences diminished over time and disappeared at 30 months.

"Interestingly, we found that patients who happened to experience a shock from the ICD within 30 days before their quality of life interview reported a significant decline in their assessment of their overall physical and emotional health," says Mark. "And those who were shocked within two months reported much the same, but with a somewhat diminished magnitude. But after one year, in comparing the 100 who had been shocked with the 638 who were not shocked, we found no significant differences in measures reflecting overall satisfaction with their quality of life."

Overall, investigators found that patients in all groups enjoyed a good quality of life despite having significant heart failure, reporting that they experienced only a modest number of days when they had to stay in bed or felt that they did not have the energy to do what they wanted to. Eighty-six percent said they were able to drive a car, 92 percent said they could manage their finances independently and 27 percent said they were still employed outside the home. Having an ICD did not appear to have any adverse effect upon these activities.

"Medical intervention almost always brings about unintended consequences. We began examining these patients when ICDs were still relatively new, and until now, we were not entirely sure that in using a device to prolong life we weren't causing additional problems in the process. We are now

happy to report that we found no evidence of that in this large trial. ICD users, on the whole, appear satisfied with the benefits and the consequences of defibrillator therapy," says Mark.

Source: Duke University Medical Center

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