Real-world patient survival with defibrillators matches trial expectations

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Patients who received an implantable heart defibrillator in everyday practice had survival benefits on par with those who received the same devices in carefully controlled clinical trials, according to a new study that highlights the value of defibrillators in typical medical settings.

Led by the Duke Clinical Research Institute and published Jan. 2, 2013, in the Journal of the American Medical Association, the study used data from a large national Medicare registry to assess the survival of patients receiving defibrillators, which are commonly used to prevent sudden cardiac death.

Because clinical trial participants tend to receive more meticulous care while also being healthier than patients seen in clinical practice, the actual benefits of new drugs and medical devices can be less positive than initially reported. Not so for the defibrillators, at least when comparing patients with similar characteristics in both the clinical trials and real-world practice.

"Many people question how the results of clinical trials apply to patients in routine practice," said lead author Sana M. Al-Khatib, M.D., MHS, an electrophysiologist and member of the Duke Clinical Research Institute. "We showed that patients in real-world practice who receive a defibrillator but who are most likely not monitored at the same level provided in clinical trials have similar survival outcomes compared to patients who received a defibrillator in the clinical trials."

"This study demonstrated the real-world applicability of the results of recent randomized clinical trials," said Alice Mascette, M.D., of the NIH's National Heart, Lung, and Blood Institute.

Implantable cardioverter-defibrillators (ICDs) have been lifesavers for people with a history of cardiac arrest or heart failure. The devices, small electrical units implanted in the chest with wires that lead into the heart, send an electronic pulse when the heart stops beating to reestablish a normal rhythm.

To monitor treatment patterns, effectiveness and safety of ICDs among Medicare patients, the Centers for Medicare & Medicaid Services mandated that data on all Medicare patients receiving a primary prevention ICD be entered into a national registry. In response to this mandate, a national ICD Registry has been collecting data from hospitals performing implantations since 2005. The Duke-led research group used data from that registry to compare more than 5,300 real-world patients against more than 1,500 patients who had enrolled in two large clinical trials of ICD devices.

Al-Khatib said the patients who were included in the analysis were selected to closely resemble the patients who participated in the clinical trials, with much older and sicker patients in the registry excluded. Both groups – study participants who received an ICD and ordinary recipients - had similar two-year and three-year survival rates. Ordinary recipients had better survival than patients in the clinical trial who did not receive an ICD. These findings were true for Medicare and non-Medicare patients.

By comparing similar populations, the researchers were able to address the concern that outcomes reported in clinical trials are overly optimistic because patients receive extraordinary care.

"We know from previous studies that many patients in real-world clinical settings don't receive the follow-up care that is recommended after the device is implanted," Al-Khatib said. She said doctors who participate in clinical trials also tend to be highly skilled specialists who do hundreds of the implantation surgeries, while physicians in ordinary practice may be less proficient. Studies have shown that patients have more complications when their doctors have less experience with a procedure.

Al-Khatib said the study had a limitation that could warrant additional examination. By eliminating Medicare patients who were appreciably older and sicker than those who enrolled in the clinical trials, the researchers were unable to determine how all patients seen in real-world practice compare to study participants.

"That is in an issue, and the only way to get at that is to randomly assign such patients to either receive an ICD or not in a clinical trial," Al-Khatib said. "Even without those data, however, our study gives patients and their health care providers reassurance that what we have been doing in clinical practice has been helpful, and is improving patient outcomes. Our findings support the continued use of this life saving therapy in clinical practice."

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