

Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure

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ABSTRACT

BACKGROUND

The benefit of an implantable cardioverter-defibrillator (ICD) in patients with symptomatic systolic heart failure caused by coronary artery disease has been well documented. However, the evidence for a benefit of prophylactic ICDs in patients with systolic heart failure that is not due to coronary artery disease has been based primarily on subgroup analyses. The management of heart failure has improved since the landmark ICD trials, and many patients now receive cardiac resynchronization therapy (CRT).

METHODS

In a randomized, controlled trial, 556 patients with symptomatic systolic heart failure (left ventricular ejection fraction, $\leq 35\%$) not caused by coronary artery disease were assigned to receive an ICD, and 560 patients were assigned to receive usual clinical care (control group). In both groups, 58% of the patients received CRT. The primary outcome of the trial was death from any cause. The secondary outcomes were sudden cardiac death and cardiovascular death.

RESULTS

After a median follow-up period of 67.6 months, the primary outcome had occurred in 120 patients (21.6%) in the ICD group and in 131 patients (23.4%) in the control group (hazard ratio, 0.87; 95% confidence interval [CI], 0.68 to 1.12; $P=0.28$). Sudden cardiac death occurred in 24 patients (4.3%) in the ICD group and in 46 patients (8.2%) in the control group (hazard ratio, 0.50; 95% CI, 0.31 to 0.82; $P=0.005$). Device infection occurred in 27 patients (4.9%) in the ICD group and in 20 patients (3.6%) in the control group ($P=0.29$).

CONCLUSIONS

In this trial, prophylactic ICD implantation in patients with symptomatic systolic heart failure not caused by coronary artery disease was not associated with a significantly lower long-term rate of death from any cause than was usual clinical care. (Funded by Medtronic and others; DANISH ClinicalTrials.gov number, NCT00542945.)

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*A complete list of investigators in the Danish Study to Assess the Efficacy of ICDs in Patients with Non-ischemic Systolic Heart Failure on Mortality (DANISH) is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on August 28, 2016, and updated on September 8, 2016, at NEJM.org.

N Engl J Med 2016;375:1221-30.

DOI: 10.1056/NEJMoa1608029

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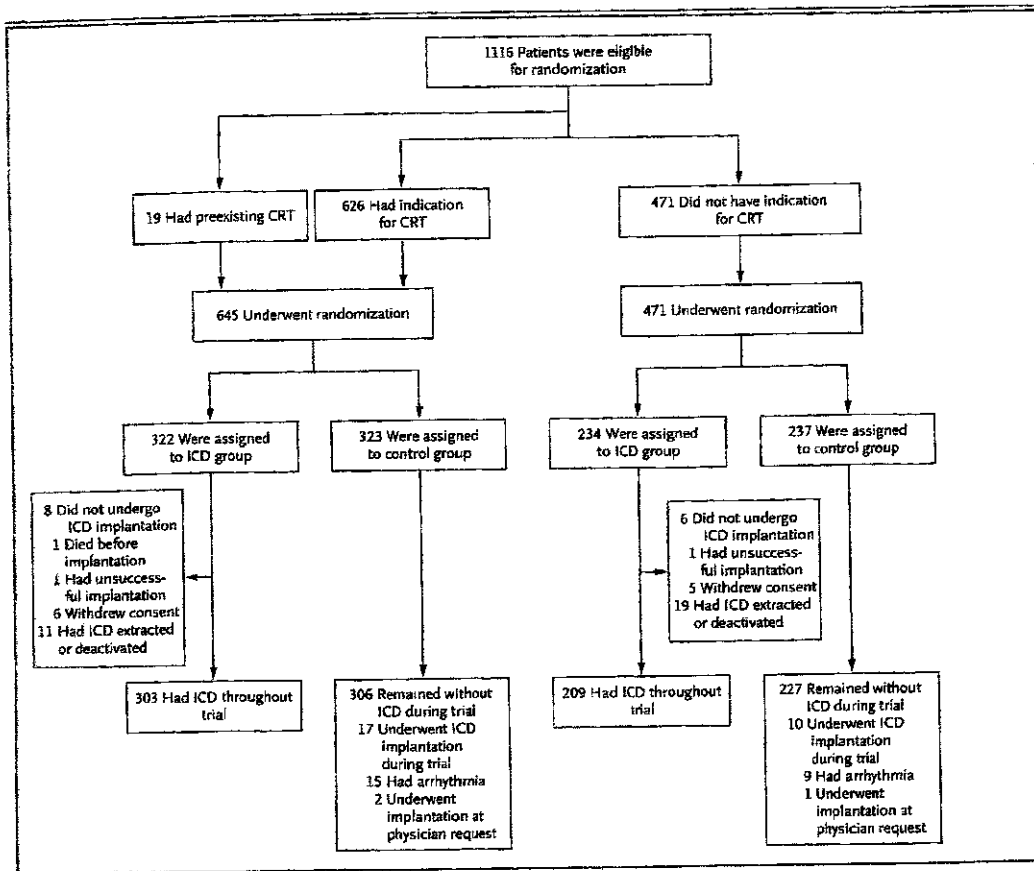


Figure 1. Enrollment and Randomization of Patients.

Details regarding device implantation and upgrades in the control group are provided in the Supplementary Appendix. CRT denotes cardiac resynchronization therapy, and ICD implantable cardioverter-defibrillator.