

Study questions generalizability of findings of CV trials for heart attack patients

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An analysis of a cardiovascular registry finds that of clinical trials that included heart attack patients, participation among eligible patients was infrequent and has been declining, and trial participants had a lower risk profile and a more favorable prognosis compared with the broader population of patients who have had a heart attack, according to a study in the August 27 issue of *JAMA*.

Jacob A. Udell, M.D., M.P.H., of the University of Toronto, and colleagues evaluated whether participants in cardiovascular trials are representative of contemporary [patients](#) with [myocardial infarction](#) (MI; [heart attack](#)). The researchers used data from the National Cardiovascular Data Registry Acute Coronary Treatment and Intervention Outcomes Network Registry-Get With The Guidelines, an ongoing, voluntary, quality improvement registry of patients with MI treated at participating centers across the United States.

Among 141,135 registry participants at 466 centers, 4,008 (2.8 percent) were trial participants; among the 137,127 nonparticipants, 93,274 were eligible (68.0 percent) and 43,853 were ineligible (32.0 percent). Overall, 255 sites (54.7 percent) enrolled at least 1 patient; and [trial participation](#) (as a proportion of eligible patients) declined each year during the study period (2008: 5.2 percent; 2009: 4.4 percent; 2010: 3.8 percent; and 2011: 3.4 percent). Trial participants were younger, with less previous cardiovascular disease, lower predicted risk of mortality, shorter hospital stays, and more frequent treatment with evidencebased therapy than nonparticipants.

Common reasons for trial ineligibility included uncontrolled hypertension, elevated INR (abnormal clotting), severe anemia, and cardiogenic shock. In-hospital mortality was lowest for trial participants, intermediate among eligible nonparticipants, and highest among ineligible patients.

"Efforts to improve trial participation are needed to enhance generalizability of results," the authors write.

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