

Aspirin and warfarin equally effective for most heart failure patients

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Neither aspirin nor warfarin is superior for preventing a combined risk of death, stroke, and cerebral hemorrhage in heart failure patients with normal heart rhythm, according to a landmark clinical trial published in today's *New England Journal of Medicine*.

The 10-year Warfarin and [Aspirin](#) for Reduced Cardiac Ejection Fraction (WARCEF) trial is the largest double-blind comparison of these medications for heart failure, following 2,305 patients at 168 study sites in 11 countries on three continents. The research was led by clinical principal investigator Shunichi Homma, MD, of Columbia University Medical Center/NewYork-Presbyterian Hospital, and statistical principal investigator John L.P. (Seamus) Thompson, PhD, of Columbia University's Mailman School of Public Health, and supported by the National Institute for Neurological Disorders and [Stroke](#) (NIH/NINDS), part of the National Institutes of Health.

In the head-to-head comparison, the combined [risk](#) of death, stroke, and cerebral hemorrhage was 7.47% per year for patients taking the blood-thinner warfarin, also known by its brand name Coumadin, and 7.93% per year for those taking aspirin—a difference that is not statistically significant.

Patients taking warfarin had close to half the stroke risk of those taking aspirin (0.72% vs. 1.36% per year). However, warfarin patients had more than twice the risk for major bleeding (1.80% vs. 0.87% per year). These results, the investigators say, cancel each other out. However, in

patients followed four years or longer, there was evidence that warfarin may be more effective in preventing the combined outcome of death, stroke, and intracerebral hemorrhage. Follow-up analyses will further evaluate this evidence and seek to identify patients for whom one of the medications is preferred.

For patients with heart failure, a weakened heart means a greater risk for blood clots that can lead to a stroke, which can be fatal or disabling. Aspirin prevents clotting and warfarin thins the blood, thus reducing the risk of stroke due to a clot or blockage in a cerebral artery. Unlike aspirin, warfarin requires a prescription and regular blood work to monitor clotting levels and adjust drug dosages.

"Since the overall risks and benefits are similar for aspirin and warfarin, the patient and his or her doctor are free to choose the treatment that best meets their particular medical needs. However, given the convenience and low cost of aspirin, many may go this route," says Dr. Homma, who is Margaret Milliken Hatch Professor of Medicine at Columbia's College of Physicians and Surgeons, and Associate Chief of the Cardiology Division at New York-Presbyterian/Columbia.

"With at least 6 million Americans—and many more around the world—suffering from heart failure, the results of the WARCEF study will have a large public health impact. Patients and their physicians now have critical information to help select the optimum treatment approach. The key decision will be whether to accept the increased risk of stroke with aspirin, or the increased risk of primarily gastrointestinal hemorrhage with warfarin," says Walter Koroshetz, MD, NINDS deputy director.

The randomized trial was double-blinded so patient and clinician were both unaware of which drug the patient was taking. The patient was instructed to take pills from two bottles, labeled aspirin and warfarin;

one was an active medication, and the other, a placebo. All patients took regular blood tests; results for patients on active aspirin were generated using an algorithm designed by Dr. Thompson. "This process gave great confidence that the trial was conducted in an unbiased way," says Dr. Thompson, who is Professor of Clinical Biostatistics and Clinical Neurology at the Mailman School and College of Physicians and Surgeons, respectively.

Previous studies established warfarin to be superior to aspirin for preventing stroke in [heart failure patients](#) with atrial fibrillation. WARCEF is the first to authoritatively answer the question for the majority of [heart failure patients](#) who have normal heart rhythm.

Provided by Columbia University's Mailman School of Public Health

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