

Study reports progress in preventing bleeding in atrial fibrillation

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A new study led by clinician-researchers at Beth Israel Deaconess Medical Center (BIDMC) testing the safety and effectiveness of anticoagulant strategies for patients with atrial fibrillation who undergo stenting procedures has shown that therapies combining the anticoagulant drug rivaroxaban with either single or dual anti-platelet therapy (DAPT) were more effective in preventing bleeding complications than the current standard of care.

Principal Investigator C. Michael Gibson, MD, Chief of Clinical Research in the Division of Cardiovascular Medicine at BIDMC, reported the new research findings today online in *The New England Journal of Medicine* and simultaneously presented the findings at the American Heart Association's Scientific Sessions 2016 in New Orleans.

The PIONEER AF-PCI randomized clinical trial involved more than 2,100 patients at 430 sites in 26 countries.

Each year, nearly 1 million patients in the United States undergo [percutaneous coronary intervention](#) (PCI) and are implanted with stents positioned to treat narrowed coronary arteries. Following PCI, patients receive dual anti-platelet therapy - a combination of aspirin and a second blood-thinning medication - to prevent the formation of blood clots in the stent. Approximately 5 to 8 percent of patients undergoing PCI have atrial fibrillation, the most common type of cardiac arrhythmia and an important risk factor for stroke. These patients typically take a blood thinner, such as warfarin (Coumadin), to prevent stroke.

"In managing the stented patient with atrial fibrillation, a pharmacologic strategy must carefully balance the risk of stent thrombosis, or blood clot, with the risk of bleeding complications," said Gibson, who is also Professor of Medicine at Harvard Medical School and chairman of the PERFUSE (Percutaneous/Pharmacologic Endoluminal Revascularization for Unstable Syndromes Evaluation) Study Group. "This trial, which tested two entirely new strategies, now provides us with [randomized clinical trial](#) data demonstrating that a combination of rivaroxaban with anti-platelet therapy is successful in minimizing bleeding while preventing clotting."

Current guidelines call for combining three drugs - DAPT plus a vitamin K antagonist (VKA) anticoagulant - in a strategy known as "triple therapy." But as the authors note, this approach may result in excess major bleeding rates of 4 to 12 percent within the first year of treatment.

The PIONEER AF-PCI trial studied men and women over age 18 with atrial fibrillation who had undergone a PCI procedure with stent placement. The study subjects were randomly assigned to one of three groups: Group 1 received reduced dose rivaroxaban plus a P2Y-12 inhibitor monotherapy; Group 2 received very low dose rivaroxaban plus DAPT; and Group 3 received VKA plus DAPT.

The findings showed that among patients with [atrial fibrillation](#) who underwent intracoronary stent placement, the administration of rivaroxaban in one of two dose strategies reduced the risk of clinically significant bleeding in about one out of every 10 to 11 [patients](#) as compared with triple therapy including a vitamin K antagonist. The risks of rehospitalization and death from all causes were also reduced in about one out of every 10 to 15 cases.

"This new treatment strategy benefits patient health as well as hospital finances," added Gibson.

Provided by Beth Israel Deaconess Medical Center

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