

Study concludes people with atrial fibrillation should not take digoxin

March 20 2017, by Sarah Avery

Amid growing uncertainty about the safety of digoxin—a commonly used heart drug—a study led by Duke Clinical Research Institute found that people with atrial fibrillation should avoid taking the drug because starting this medication is associated with higher death rates.

The finding was reported Sunday at the American College of Cardiology 66th Annual Scientific Session meeting in Washington, D.C.

"Although its general use has declined over the past 30 years, [digoxin](#) is still used by as many as one-third of [atrial fibrillation patients](#) worldwide," said lead author Renato D. Lopes, M.D., Ph.D., professor of medicine and member of the Duke Clinical Research Institute. "There have been several studies questioning the safety of this drug in patients with atrial fibrillation, and different analyses looking at different questions have shown conflicting results. Yet current guidelines still have digoxin as a treatment option for patients with atrial fibrillation.

"Our study provides a strong, comprehensive, and up to date evidence—short of a randomized, control trial—that starting digoxin is associated with an increased risk of [death](#) in patients with atrial fibrillation," Lopes said. Digoxin is generally used to strengthen the heart's contractions and to control the heart rate.

Lopes and colleagues analyzed data from a large, international clinical trial called ARISTOTLE, which was undertaken to compare warfarin to apixaban as a stroke prevention for patients with atrial fibrillation.

In a subsequent analysis to examine whether digoxin was associated with mortality, the researchers examined deaths from all causes, including cardiovascular and non-cardiovascular deaths among a total of 17,897 atrial fibrillation patients in the database.

Of those patients, 5,824 (32.5 percent) were on digoxin at the start of the study, and 6,693 (37.4 percent) had heart failure. Another 873 patients (6.9 percent) started the drug at some point during the study.

The researchers found that in patients already receiving digoxin and, therefore more likely to tolerate it, the overall relationship between digoxin use and death was non-significant. However, even among those patients, the risk of death was related to digoxin concentration in the blood: for every 0.5 nanograms per milliliter increase in the blood level of digoxin, the risk of death rose by 19 percent. Among patients whose digoxin levels were greater than 1.2 ng/mL, the death rate significantly increased by 56 percent.

"Additionally, death risks—and particularly sudden death—were substantially higher in patients who began digoxin after the start of the study," Lopes said. "Most of the deaths occurred in the first six months after digoxin was initiated."

Lopes said the full scope of the study and its independent findings add up to the conclusion that the drug should not be used by patients with atrial fibrillation, particularly if symptoms can be alleviated with other treatments. He added that in atrial fibrillation patients already taking digoxin in whom treatment is deemed necessary, monitoring digoxin serum concentration is important to ensure that blood levels stay below 1.2ng/mL.

"Although our study results speak in favor of causation between digoxin use and increased risk of death, this is an observational study, and

causation cannot be definitively established," Lopes said.

"Definitively determining the efficacy and safety of digoxin in patients with atrial fibrillation would require a large and well-powered randomized trial," Lopes said. "Until then, our finding that digoxin may be causing more harm than good in patients with atrial fibrillation is important and could help guide physicians in their clinical decisions when managing these patients."

Provided by Duke University

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