

ROCKET AF trial suggests that digoxin increases risk of death in AF patients

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Digoxin may increase the risk of death in patients with atrial fibrillation (AF) by approximately 20%, according to results from the ROCKET AF trial presented at ESC Congress today by Dr Manesh Patel, director of interventional cardiology and catheterisation labs at Duke University Health System in Durham, North Carolina, US. The findings suggest that caution may be needed when using digoxin in complex AF patients but further studies are needed to confirm the observations.

Dr Patel said: "In this subanalysis of the ROCKET AF trial we found that AF <u>patients</u> who took the drug <u>digoxin</u> had an <u>increased risk</u> of adverse cardiovascular events, including vascular death or sudden death."

He added: "Digoxin, which works to strengthen heart contractions, is one of the oldest medications used in the treatment of patients with heart failure and it has also been used in patients who have AF. However the use of digoxin in AF patients has not been rigorously studied in randomised trials. We therefore conducted a retrospective subanalysis of the ROCKET AF trial to determine the effect of digoxin on the risk of death in patients with AF."

The ROCKET AF trial was a double-blind trial conducted in 14 171 patients with nonvalvular AF who were at increased risk of stroke. The study took place at 1 178 sites in 45 countries. Patients were randomised to take either rivaroxaban or warfarin for anticoagulation. The trial found that in patients with AF, rivaroxaban was non-inferior to warfarin



for the prevention of stroke or systemic embolism.

In the current analysis, the researchers examined the risks of all cause mortality and cardiovascular mortality in 5 239 patients taking digoxin at the start of the study, compared to 8 932 patients who were not taking digoxin.

The researchers found that the use of digoxin was associated with a 22% increased risk of death due to any cause and a 22% increased risk of <u>death</u> due to a cardiovascular event.

Dr Patel said: "Our analysis represents an important observation with digoxin use in patients with <u>atrial fibrillation</u>. Digoxin could potentially be harmful and we need randomised trials to determine whether it can be used patients with atrial fibrillation. Our findings suggest that doctors should proceed with caution when using this drug for complex AF patients."

Dr Jeffrey Washam, a clinical pharmacist at the Duke Heart Center and first author of the abstract, said: "Despite being one of the oldest therapeutics in heart care, we still know very little regarding the risks and benefits of digoxin when used in patients with atrial fibrillation. In complex patients with atrial fibrillation, this analysis highlights the need for well-controlled studies to evaluate the efficacy and safety of digoxin."

Dr Patel concluded: "The results from this study should be confirmed in a prospective randomised trial."

Provided by European Society of Cardiology

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