The RATE-AF trial: Summary of results for patients. Written by the Patient and Public Involvement Team.



The RATE-AF trial was sponsored by the University of Birmingham (Chief Investigator: Professor D Kotecha; Research Fellow: Dr Karina Bunting).

The RATE-AF trial was funded by the National Institute for Health Research (NIHR).

The opinions expressed in this summary are those of the authors and do not represent the NIHR or the UK Department of Health and Social Care.

The full scientific publication of the trial results can be found on:

https://jamanetwork.com/journals/jama/fullarticle/2774407

On behalf of the entire study team, thank you for your participation in the RATE-AF trial.

About atrial fibrillation (AF)

AF is a common heart condition that leads to an irregular and often rapid heart rate. AF can cause a stroke, and patients have frequent admissions to hospital. In addition, AF makes many patients feel unwell, with reduced quality of life.

What was the purpose of the RATE-AF trial?

AF usually requires medication to control heart rate, but we currently don't know which medication is better for patients. The aim of the RATE-AF trial was to compare two treatments commonly used in those with constant (permanent) AF who have symptoms suggestive of heart strain or failure of the heart pump:

- 1. Beta-blockers such as bisoprolol are one of the most common drugs used in clinical practice to control heart rate in patients with AF. They are also widely used for other heart diseases, and work to counter the response to adrenaline/epinephrine in the body.
- 2. Digoxin to treat patients with heart disease was first described over 230 years ago. Nowadays, it is mostly used in patients with AF, commonly when they also have heart strain. However, in all this time, there has never been a direct comparison in a clinical trial of these patients. Digoxin was originally extracted from the leaves of the digitalis plant, and works slowly to improve the contraction of the heart. It also has a broad range of other effects, which at low-dose can potentially be helpful to counter the body's response to AF and heart strain.

We compared these two drugs in a random fashion in 160 patients, to avoid the bias by clinicians that usually exists in the choice of treatment. The design and management of the trial were assisted by a Patient and Public Involvement team. The outcomes of the trial were focused on patient-reported quality of life at 6-months and 12-months, the impact of AF on daily life, measures of heart strain, and the safety and patient satisfaction of treatment.

Summary of the trial findings

Both drugs were found to successfully control heart rate in patients feeling unwell from their AF. The main outcome of the study, which looked at quality of life from a physical perspective, was no different between digoxin and bisoprolol, suggesting that either drug can be used to improve quality of life. Digoxin was found to cause fewer side effects than beta-blockers, and lessened the impact of AF on the daily lives of patients by improving symptoms. Compared to beta-blockers, digoxin also lowered the stress on the heart at 12-months. In summary, the RATE-AF trial has shown that 12-month treatment with digoxin is safe and effective, and has the same effect on physical wellbeing as beta-blockers for patients with permanent AF.

Implications for patients

Patients should continue to take the medications they are currently prescribed for their AF. There may be other reasons your doctor has selected a particular drug for you, and stopping any treatment could have potentially bad effects on your health. For example, beta-blockers are commonly used to control blood pressure and manage coronary artery disease. Patients aged 60 years or older with permanent AF and heart strain, whose main concern is to improve their day-to-day symptoms, could discuss with their healthcare team if digoxin might be right for them. Larger trials are needed to see if digoxin can reduce the need for hospital visits. Please remember that these drugs are used to control AF, and most patients will also benefit from blood thinners to prevent strokes and blood clots.

Patient support

Patient information from the British Heart Foundation: https://www.bhf.org.uk/heart-health/conditions/atrial-fibrillation.

Education and support groups for patients and carers from the Heart Rhythm Alliance: https://www.heartrhythmalliance.org/.

Free smartphone and tablet apps for healthcare professionals and patients with AF from the European Society of Cardiology: www.escardio.org/af-apps.