Safety indicators confirmed for common treatment of heart defect

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A new study by medical scientists coordinated from the University of Manchester has for the first time used patients' results to establish that "safety indicators" for people taking anticoagulant drugs to regulate a common heart condition are correct.

More than 760,000 patients in the UK have atrial fibrillation (AF), a defect that causes an irregular heart rate. It is also known to increase the risk and severity of stroke.

The main treatment used to regulate the condition is an anticoagulant drug called warfarin which prevents the blood from forming clots so easily. This treatment also lowers the risk of a stroke by about two thirds.

The recommendation to use anticoagulation for patients with AF was circulated to all NHS hospitals and practices last year in a Commissioning Safety Document.

However, there are risks associated with the drug as too little anticoagulation results in thrombosis but too much can result in haemorrhage. Both can be fatal. Patients therefore require frequent monitoring and dose adjustments.

Part of monitoring is measuring a patients' international normalized ratio (INR). In healthy people, the INR is about 1.0. For patients on anticoagulants, the INR typically should be between 2.0 and 3.0.

However there had been no large scale studies to establish the danger INR level in patients with AF.

Medical scientists working with the European Action on Anticoagulation which is organised from the University of Manchester tested 5839 patients with AF. The INR for each case was monitored by blood tests which were independently assessed. Any clinical events, such as bleeding or thrombosis, were also monitored and matched to the patient's INR reading.

The study found that in patients starting to take anticoagulation therapy who had a bleeding episode 9.5% had at least one INR result that was greater than 5.0. This was significantly higher than in the 4.6% of patients who had a bleeding episode but did not develop an INR greater than 5.0.

In the first two months of treatment, bleeding occurred in 11.0% of patients who had at least one incidence of an INR greater than 5.0. Whereas the bleeding rate in patients who never recorded an INR greater than 5.0 was only 5%.

Professor Leon Poller, the Project Leader of the European Action on Anticoagulation said: "This study demonstrates through significant patient results that the "safety indicators" listed in last year's UK NHS Improvement Document are correct. This is a really important finding for the hundreds of thousands of patients in the UK who suffer from AF and for the medical staff who treat them."

The results of the study are being made available to all NHS hospitals and practices and have been published in the current issue of the *Journal of Clinical Pathology*.

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Provided by University of Manchester

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