ICU
MANAGEMENT & PRACTICE

ICU Volume 12 - Issue 2 - Summer 2012 - Research News

FDA to Review CV Risk With Azithromycin

The US Food and Drug Administration (FDA) will review a new study in which it is indicated that patients taking azithromycin are at a slightly increased risk of sudden cardiac death than patients treated with amoxicillin, ciprofloxacin, or no antibiotic at all.

The observational study entitled “Azithromycin and the Risk of Cardiovascular Death”, which was published on May 17,

2012, in the New England Journal of Medicine (NEJM), looked at Medicaid patients on a five day course of azithromycin. The FDA made the announcement to look into the study that same day.

The agency recapped that QT interval prolongation, which can trigger an abnormal and sometimes fatal heart arrhythmia called torsades de pointes (TdP), has been linked not only with azithromycin but also with other antibiotic drugs in the macrolides class. Drugs in this group include clarithromycin and erythromycin, neither of which figured into the NEJM study.

Concern on the risk for cardiovascular death for patients taking the macrolides class of antibiotics has been on the FDA's radar since 2011, when it evaluated the labels for these drugs.

In March, the FDA revised the warnings and precautions section of an extended-release, oral suspension version of azithromycin. It added mention of reports of QT interval prolongation and TdP and advised clinicians to avoid prescribing the antibiotic for patients with known QT interval prolongation, patients with low potassium, or those taking drugs that prolong the QT interval. The labels for clarithromycin and erythromycin also warn of reports regarding QT interval prolongation. Labels of other macrolides will also be reviewed by the agency.

Officials at the FDA said that the agency would update the public regarding azithromycin and the potential risk for QT interval prolongation after it has reviewed the NEJM study. Patients taking azithromycin are advised by the FDA not to stop taking it without first consulting a clinician.

www.medscape.com

Published on : Sat, 14 Jul 2012