

Azithromycin and the Risk of Cardiovascular Death

On May 17, 2012, the New England Journal of Medicine published a study that compared the risk of cardiovascular death when treating patients with azithromycin, amoxicillin, ciprofloxacin, or levofloxacin. The study reported that patients taking azithromycin compared to those not taking antibiotics for 5 days were at a small increased risk of cardiovascular death. The results also showed that cardiovascular death was similar between azithromycin and levofloxacin. Patients who took amoxicillin or ciprofloxacin did not have an increased risk of cardiovascular death.

Azithromycin is an antimicrobial agent that belongs to a class of drugs called macrolides. It has approved indications to treat a variety of conditions including bacterial sinusitis, community-acquired pneumonia, urethritis and cervicitis, pharyngitis and tonsillitis, and respiratory tract, skin, and soft tissue infections. Studies have shown that treatment with macrolides has caused prolonged QT intervals in patients. A prolonged QT interval can lead to potentially fatal torsades de pointes.

Following the publication of the study, on March 12, 2013, the FDA released a public drug safety warning that azithromycin can lead to potentially fatal irregular heart rhythm due to the changes in electrical activity of the heart. Patients with existing prolonged QT intervals, low serum potassium and magnesium levels, slow heart rate, arrhythmias, or use medications to treat abnormal heart rhythm are at increased risk.

The FDA noted that aside from azithromycin, other antimicrobial medications in the same drug class and in different classes has also shown to be QT prolonging agents. They recommend health care providers be aware of the potential risk of torsades de pointes and abnormal heart rhythms when considering treatment options for patients with identified risk factors. The warning and precautions section of the azithromycin label has been updated with information regarding the risk of QT prolongation.

References:

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