Global Drug Safety Insights From Taiwan

Joseph S. Ross, MD, MHS

The investments made by the government of Taiwan to create the Taiwan National Health Insurance Research Database continue to realize global population health benefits. The database has been used to conduct numerous studies of drug safety and efficacy, diagnostic test utility, disease progression, and risk factor prognosis, generating important clinical and public health insights that have implications not only for the people of Taiwan but also for people around the world. The article by Lee et al on fluoroquinolone safety in this issue of JAMA Internal Medicine adds to this knowledge.

Fluoroquinolones are among the most widely used antibiotics in the world because of broad gram-positive and gram-negative coverage, excellent oral bioavailability, and, thus far, manageable resistance patterns. More than 20 million individuals received an outpatient prescription in the United States in 2011 alone, nearly 4 million in the hospital setting. However, despite being generally well tolerated, rare serious adverse effects have been reported, and there is a class-level black box US drug label warning of an increased risk of tendinitis and tendon rupture, possibly secondary to the fluoroquinolones’ effect on collagen, and of muscle weakness exacerbation in persons with myasthenia gravis.

Using case-control methods to analyze the Taiwan National Health Insurance Research Database, Lee et al examine a related, and serious though rare, collagen-based drug safety concern: aortic aneurysm and dissection, finding a nearly 3-fold increased risk of aortic aneurysm and dissection among fluoroquinolone users. Risk for this serious yet rare adverse event should be considered in any benefit-risk calculation for fluoroquinolone use, and further research into the impact of these important antibiotics effect on collagen is needed. However, physicians and other health care professionals should be aware of this potential risk so that they can act swiftly to address aortic aneurysms and dissections when they do occur.

Conflict of Interest Disclosures: Dr Ross receives research grant funding through Yale University from the US Food and Drug Administration to develop methods for postmarket medical device surveillance and from Medtronic Inc and Johnson & Johnson to develop methods for clinical trial data sharing.


Editor’s Note

Related article page 1839