Hot Topic
New Labeling for Fluoroquinolones

Darrell Hulisz, RPh, PhamD
Associate Professor, CWRU School of Medicine
Amanda Scharf, Pharmacy Intern
Ohio Northern University, College of Pharmacy

The Food and Drug Administration recently strengthened warning labels on fluoroquinolone antibiotics to address the serious risks associated with using these antibiotics for minor infections. A review panel was formed by the FDA in November 2015 to evaluate the safety of fluoroquinolones. The panel concluded that alternative agents should be administered when possible for the treatment of acute sinusitis, mild bronchitis, and uncomplicated urinary tract infections because the risks outweigh the benefits in these situations.

In the case of mild bronchitis, antibiotics are generally not recommended. For treatment of acute bacterial sinusitis, the Infectious Diseases Society of America (IDSA) recommends beta lactam therapy for patients with more severe sinusitis symptoms. IDSA guidelines claim that acute sinusitis is caused by a virus in 90% of cases, and that symptoms generally resolve within two weeks without intervention. Similarly, fluoroquinolones are not recommended as first line agents in uncomplicated urinary tract infections. Restricting the use of fluoroquinolones in these uncomplicated infections can help prevent serious adverse effects and help curb antibiotic resistance.

Systemic fluoroquinolones have been shown to adversely affect tendons, nerves, the heart, and the central nervous system in patients of all ages. Risk factors for tendonitis or tendon rupture are increased in the elderly, patients on steroid therapy, and transplant patients. Neurological side effects associated with fluoroquinolones include seizures, tremors, mental status changes, increased intracranial pressure, pseudotumor cerebri, and psychosis. In 2013 irreversible peripheral neuropathy was added as a warning to fluoroquinolones. In regards to cardiovascular risks, fluoroquinolones are associated with QT prolongation. Other serious complications of these antibiotics is myasthenia gravis exacerbations and phototoxicity. Fluoroquinolones currently have boxed warnings for tendon rupture, tendonitis, and myasthenia gravis. Although the frequency of these complications is relatively low, the severity of these effects can be disabling and permanent. The onset of these side effects range from a few hours to several months.

The FDA panel reviewed disability reports associated with the treatment of uncomplicated urinary tract infections, bronchitis, and sinusitis that were sent to the FDA Adverse Event Reporting System. A disability report was defined as a major disruption in an individuals ability to perform activities of daily living. The review discovered that compared to nine other antibacterial medications used to treat these infections, fluoroquinolones had the highest rates of causing disability with rates ranging from about 10% to 31%. Complications involving the musculoskeletal, neuropsychiatric, and peripheral nervous systems were the most commonly reported and reports were similar across the oral fluoroquinolones.

Pharmacists and other health care providers should counsel patients to seek medication attention if they experience symptoms such as tendon, muscle, or joint pain, hallucinations, "pins and needles" tingling or pricking sensation. The seriousness of these adverse reactions and the possibility that they can occur simultaneously is a major concern. Interestingly, the number of fluoroquinolone prescriptions did not decrease after the box warning for tendonitis and tendon rupture in 2008, or the special warning about peripheral neuropathy in 2013. These warnings should be taken more seriously in light of the adverse consequences fluoroquinolones can cause and the potential for antibiotics to be unnecessary in some of these patients with minor infections.

References

1. Food & Drug Administration. FDA approves safety labeling changes for fluoroquinolones. July 26, 2016. http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm500325.htm
2. Food & Drug Administration. FDA updates warnings for fluoroquinolone antibiotics. July 26, 2016.http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm513183.htm
3. IDSA Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adults. March 20, 2012.http://cid.oxfordjournals.org/content/early/2012/03/20/cid.cir1043.full