Drug Monitor

Evaluating the Safety of Warfarin in the LTC Setting

Of the more than 1.6 million Americans who currently reside in long-term care (LTC) facilities, it's been estimated that approximately 200,000 receive warfarin. Considering warfarin's potential for adverse effects and interactions, as well as the frailty of many LTC patients, how well are these facilities protecting their patients' safety? Researchers from the University of Massachusetts Medical School, Worcester, MA; New York University School of Medicine, New York, NY; and Duke University School of Medicine, Durham, NC set out to discover how often warfarin-related treatment errors occur in LTC facilities and how many of these errors are preventable.

Over 12 months, the researchers studied a cohort of residents from 25 Connecticut nursing homes, with the total number of residents ranging from 2,946 to 3,212 per quarter. Trained nurse abstractors reviewed records each quarter to identify possible warfarin-related incidents. Two physician reviewers then independently determined whether each incident represented an adverse warfarin-related event (defined as injury associated with warfarin use) or a potential adverse warfarin-related event (defined as a situation in which there was no injury but the international normalized ratio was 4.5 or greater and an error in warfarin management occurred). They further classified the severity and preventability of all adverse warfarin-related events.

During the study period, 490 residents were receiving warfarin therapy. The researchers detected 720 adverse warfarin-related events and 253 potential adverse warfarin-related events. Of the 720 adverse events, 207 (29%) were deemed preventable.

While the majority of adverse events (625, or 87%) were classified as minor, 82 (11%) were considered serious, eight (1%) were life threatening, and five (less than 1%) resulted in death. Of the 13 life threatening or fatal events, 11 were deemed preventable.

Among all of the preventable events, the most common treatment errors occurred with warfarin prescribing or monitoring—with 285 (62%) involving both types of errors. Prescribing errors usually were related to a wrong dose (81%) or a known drug interaction (25%), while monitoring errors generally involved inadequate laboratory monitoring of warfarin therapy or a delayed response or lack of response to laboratory results.

According to the researchers, inefficient communication is often to blame for warfarin errors in the LTC setting. Since most nursing homes work with outside physicians, laboratories, and pharmacy vendors, opportunities for miscommunication are frequent—for instance, when a nurse informs a physician by telephone about a patient with a urinary tract infection but fails to mention that the patient is taking warfarin. Futhermore, the researchers say, most nursing homes are not ready to implement costly new technologies, such as computerized physician order entry, that may or may not prevent errors. They advise that protocols be developed and tested to improve the accuracy of warfarin-related information communicated to prescribers. Additionally, they recommend a strengthened educational campaign on the safe use of warfarin in the LTC setting.

Source: *Am J Med.* 2007;120(6):539–544. doi:10.1016/j.amjmed.2006.07.045.

New Treatment Approved for Pulmonary Arterial Hypertension

The FDA has approved ambrisentan (Letairis, Gilead Sciences, Inc., Foster City, CA)—a nonsulfonamide, propanoic acid-class, endothelin receptor antagonist that is selective for the endothelin type-A receptor—to treat pulmonary arterial hypertension (PAH). The FDA gave ambrisentan a priority review and, due to the rarity of PAH, has granted it orphan drug status. According to John Jenkins, MD, director of the FDA's Office of New Drugs, ambrisentan is similar to an existing PAH drug but "offers the potential for fewer drug interactions."

Two international clinical trials, involving 393 patients, demonstrated that ambrisentan significantly improved physical activity capacity, compared with placebo, and delayed PAH progression. The most common adverse effects were edema of the legs and ankles, nasal congestion, sinusitis, and flushing.

Ambrisentan is contraindicated in pregnancy. As such, providers must exclude pregnancy before prescribing the drug and advise patients to practice two reliable methods of contraception during therapy. In addition, since the drug can cause large increases in serum levels of aminotransferases, which could lead to liver injury, patients should have these levels tested prior to treatment and monthly thereafter. Ambrisentan is available in 5- and 10-mg tablets to be taken once daily. ●

Sources: FDA news release. June 15, 2007.

Letairis new drug application. http://www.drugs.com/nda/ambrisentan_070216.

Letairis [prescribing information]. Foster City, CA: Gilead Sciences, Inc; 2007.