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Drug Safety News in 80 Seconds (2009-02)

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REGULATORY NEWS

- **EU recommends avoidance of all PPIs with clopidogrel:** The EU Committee for Medicinal Products for Human Use has evaluated the available evidence and concluded that PPIs do hinder the ability of clopidogrel to reduce heart attacks and coronary artery restenosis. Since there is insufficient evidence to distinguish between the PPIs, they recommend avoidance of all PPIs in patients using clopidogrel unless considered essential. Patients should be referred to their physician to assess their treatment. H2 blockers are not known to cause this interaction, but data are lacking. [1]
- **Challenge to Canada`s Direct-to-Consumer-Advertising (DTCA) laws put on hold:** In 2005, CanWest MediaWorks challenged the federal government on its prohibition of DTCA, arguing that it infringes on the Canadian Charter of Rights and Freedoms, specifically "freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication." But the Attorney General of Canada states that the Charter guarantees rights and freedoms "subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society" and that the ban on DTCA is for the protection of Canadians. YouTube videos on the subject can be found at: http://www.youtube.com/watch?v=oSk7IP_Yljw and <http://www.youtube.com/watch?v=C7FGtYVQMFc&feature=fvw>. [2]
- **Genetic link for flucloxacillin-induced liver damage:** The FDA and an international consortium have linked the HLA-B*5701 genotype with an increased risk of liver damage in patients given flucloxacillin. Eventually this type of research may prevent drug-related liver damage. [3]
- **New safety warnings from Health Canada:** The fastest way to find Health Canada drug safety information is to go to www.medeffect.ca and look under Advisories, Warnings and Recalls. Recent safety concerns include etanercept and invasive fungal infections; trastuzumab and oligohydramnios; erlotinib and GI perforations, Stevens Johnson syndrome and corneal perforations; mycophenolate and pure red cell aplasia; removal of approval for the use of piroxicam to treat short-term pain, due to relatively high risks of skin reactions and GI problems; and numerous foreign product alerts

(notably Reducing Weight Easily, found to contain sibutramine, phenolphthalein perhaps for its laxative effect, and lead). Case reports contributed to the safety reviews for some of these products, so don't forget to report to Health Canada!

- **The FDA and Health Canada warn against using Zycam:** The FDA has received more than 130 reports of loss of smell in patients using Zycam nasal zinc products, marketed for relief of cold symptoms. This is a serious adverse reaction that may be permanent, and it has occurred following a single exposure. [4]
- **Cancer concerns:** Three types of drugs have recently been investigated with respect to their risk of causing cancer. It is very difficult to determine the validity of these suspicions. Some of the evidence comes from observational studies, which cannot be used to prove a causal link. One of the possible weaknesses of observational studies is confounding by indication: sicker patients may have been more likely to be placed on these drugs and may be at greater risk of cancer because of their underlying comorbidities, not because of the drugs, leading to an overestimate of the risk. On the other hand, cancer may be hard to detect in the relatively short-term studies used, leading to an underestimate of the risk.

1. The FDA and Health Canada are reviewing concerns about cancer and Lantus: Recently published observational studies suggest a link between Lantus (insulin glargine) and cancer. Since observational studies cannot prove a causal link, the subject is under review; in the meantime, patients should not change their insulin therapy without consulting a physician. [5]
2. Concern about TNF inhibitors: An observational study looking at the risk of mortality or cancer mortality with immunosuppressive drugs found a more than three-fold increased risk of cancer mortality with TNF inhibitors, and no risk with other immunosuppressives. Few patients in the study were taking TNF-inhibitors, however, and the results are based on 11 deaths occurring in 213 patients. The confidence intervals are broad: adjusted Hazard Ratio 3.83, 95% CI 1.13 to 13.01. [6]
3. Concern about lipid-modifying drugs and cancer: The important ongoing question of the potential for statin drugs to increase the risk of cancer was investigated in a new meta-analysis of randomized controlled trials done in patients without diagnosed cardiovascular disease, and no increase in cancer risk was found. [7] However, the average length of follow-up was only 5 years; longer term safety data are needed.

CLINICAL STUDIES AND CASES

- **Once yearly zoledronic acid for osteoporosis and fatal cases of renal failure:** The FDA has received 24 cases of renal impairment following IV administration of zoledronic acid. There were 4 deaths from acute renal failure; causality is unclear. [8]
- **Alka-Seltzer containing ASA for stomach disorders questioned:** An article in the journal Drug Safety criticizes the marketing of Alka-Seltzer for indigestion, stomach upset and heartburn. [9,10] The authors note that ASA is not proven to reduce stomach upset symptoms and can increase GI irritation and bleeding.
- **Inadvertent exposure to testosterone gel in children:** Enlarged genitalia, premature pubic hair, advanced bone age, increased libido and aggression have been reported in children following skin contact with adults who had applied testosterone gel. In some cases the genital and bone effects were not fully reversible. [11]

Expect the Unexpected:

Sometimes an apparent adverse drug reaction is not caused by the drug. Consider the recent case reported of a patient who had been taking atorvastatin for elevated LDL-cholesterol for many years. When his dose of atorvastatin was increased, he developed muscle pain and a tired feeling in his legs when walking upstairs. Suspecting statin-induced myopathy, his creatine kinase levels were measured and were indeed elevated. The statin was discontinued. Surprisingly, the creatine kinase level did not normalize and the muscle pain persisted. Laboratory investigation revealed the real problem: hypothyroidism. Treatment with levothyroxine relieved the myalgia and elevated creatine kinase levels. Hypothyroidism commonly produces elevated LDL cholesterol as well as muscle pain, weakness and elevated creatine kinase levels. Consider hypothyroidism in patients who develop muscle problems while taking a statin if drug discontinuation does not help. [12]

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