IDIS Independent Drug Information Service

PEARL:
Prompt Evidence Assessment and Review of the Literature

Is there an association between proton pump inhibitors (PPIs) and fractures?

The clinical issue: In May 2010, the U.S. Food and Drug Administration (FDA) revised the prescription and over-the-counter (OTC) labels for proton pump inhibitors (PPIs) to include new safety information about a possible increased risk of fractures of the hip, wrist, and spine with the use of these medications.

The new evidence: To date, randomized clinical trials have not found an increased risk of fractures of the hip, wrist, or spine with PPIs. The new safety information is based on the FDA's review of 7 epidemiological studies that reported on the risk of fractures of the hip, wrist, and spine with PPI use.

In Summary:

- ☑ Six of the seven studies reported an increased risk of fractures associated with PPI use. The seventh study was limited to individuals without major risk factors for fracture.
- ☑ This increased risk of fracture was primarily observed in people ≥ age 50.
- ☑ Two studies reported an increase in fractures with higher doses of PPIs, and two studies reported an increase in fractures with longer duration of use.

What should we do with this information: Based on the available data, it has not been definitively established that PPIs cause the increased risk of fractures seen in these studies. The FDA plans to analyze data from several large, long-term, placebo-controlled clinical trials of bisphosphonates, to assess the risk of fractures in patients who used or did not use PPIs. Despite this uncertainty, clinicians should consider using the lowest dose and shortest duration of PPI therapy that will adequately treat the patient's condition

Where can we get more information?
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213206.htm

This material was produced by Niteesh K. Choudhry, M.D., Ph.D., Assistant Professor of Medicine, Harvard Medical School and Danielle Scheurer, M.D., M.Sc., F.H.M., Assistant Professor of Medicine, Medical University of South Carolina, for the Independent Drug Information Service (iDiS).

These are general recommendations only; specific clinical decisions should be made by the treating physician based on an individual patient's clinical condition.

The Alosa Foundation

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