

Pradaxa Noted For Possible Heart Attack Risk In Addition To Serious Gastrointestinal Bleeding And Other Hemorrhages

Recent Medical Article And Poster Presentation Both Point To A Trend Toward Increased Rate Or Risk Of Myocardial Infarction (MI)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on April 24,2012; see <http://bit.ly/JXteok>)

A recent "position paper" by a group of experts from the European Society of Cardiology (ESC) Working Group on Thrombosis provides an update on the side effects associated with Pradaxa (dabigatran). In part, it pointed out there is increasing evidence of heart attacks, or myocardial infarction (MI), in patients using this relatively new anticoagulation drug from Boehringer Ingelheim.

In "[New Oral Anticoagulants in Atrial Fibrillation and Acute Coronary Syndromes: ESC Working Group on Thrombosis-Task Force on Anticoagulants in Heart Disease Position Paper](#)", published in April 2012 by the *Journal of the American College of Cardiology*, these ESC experts noted some specific Pradaxa side effects "such as an increased rate of dyspepsia and gastrointestinal bleeding, [as well as] a trend toward an increased risk of myocardial infarction...."

A second development about the Pradaxa - heart attack connection came out of the March 2012 American College of Cardiology (ACC) meeting in Chicago. In particular, a so-called "poster" presentation, "[Dabigatran and Myocardial Infarction, Drug or Class Effect. Meta-analysis of Randomized Trials with Oral Direct Thrombin Inhibitors](#)", provided this information about Pradaxa and heart attacks:

Background: The recent trial on dabigatran versus warfarin in Atrial Fibrillation (RE-LY) demonstrated dabigatran 150 mg twice daily was associated with small but statistically significant increased number of Myocardial Infarction (MI) as compared to warfarin. The purpose of this study was to investigate whether this finding was due to Drug or Class effect.

Methods: We systematically searched MEDLINE using key words, oral, direct thrombin inhibitors and randomized trials. Studies were included in Meta-Analysis if comparison between an oral direct thrombin inhibitor and warfarin was made for any indication and if data on Myocardial Infarction after randomization was available....

Conclusions: 1) Our findings suggest an overall trend toward increased rate of myocardial infarction for patients treated with oral direct thrombin inhibitors and dabigatran in particular as compared to warfarin. This trend is statistically significant and may be suggestive of a class effect based on Fixed effect model Meta-Analysis. 2) Clinicians involved in the care of patients with coronary artery disease may need to exercise caution in the use of these agents. 3) Further research is needed to address these concerns.

The possibility that patients who use Pradaxa have an increased risk for heart attack was [first given some profile with a study report published in early January 2012](#) by the *Archives of Internal Medicine*.

The April 2012 ESC "position paper" as well as the March 2012 ACC "poster" presentation, however, seem to indicate that there is growing concern about a Pradaxa heart attack side effect.

To this point in time, and still, most of the scrutiny on Pradaxa from drug safety regulators and others had been about hemorrhages, including gastrointestinal bleeding, as seen from these prior posts:

- [Pradaxa: FDA Investigating Possible Higher Than Expected Incident Rate Of Serious Bleeding Side Effects](#)
- [Pradaxa: 2012 Label Revisions In The U.S. And Canada, Where A "Dear Doctor" Letter Was Sent Out](#)

We will continue to track Adverse Event Reports (AERs) regarding Pradaxa and let you know about significant developments here at Drug Injury Watch.

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
<http://www.DrugInjuryWatch.com>