

## Pradaxa Hemorrhage Cases May Occur In Oldest Patients Due To Age-Related Decline In Renal Function

### ***QuarterWatch* 2011 Quarter 2: More Pradaxa Adverse Events Reported Than Any Other Regularly Monitored Drug**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on April 16, 2012; see <http://bit.ly/HNKEa4> )

The developing drug safety controversy involving the anticoagulation drug Pradaxa (dabigatran) has been presented best, perhaps, by the ISMP *QuarterWatch* publication, which served as the basis for these two past articles about the problems with Pradaxa:

(1) [New Heart Drug Pradaxa May Be Sending "Early" Drug Safety Signals](#) -- ISMP *QuarterWatch* 2010 4th Quarter: Hemorrhages And Thromboembolic Events Have Been Reported To FDA

(2) [Pradaxa: Excess Number Of Severe Bleeding Events In Certain Patient Populations And Settings](#) -- At Increased Risk Are Patients Who Are Older, Have Altered Renal Clearance, Or Undergoing Atrial Fibrillation (AF) Ablation (citing the ISMP *QuarterWatch* 2011 Quarter 1 edition)

And the latest Pradaxa safety "update" comes from [ISMP QuarterWatch 2011 Quarter 2](#) (PDF), which was released April 5, 2012:

[(Pradaxa (dabigatran)] a new anticoagulant intended to reduce the risk of stroke, was a suspect drug in 856 reported cases, more than any other regularly monitored drug, but showed a decrease from 931 reports in the previous quarter. The new quarterly total included 117 reported patient deaths. With 511 reported cases of hemorrhage, and a median patient age of 80 years, these new bleeding reports reinforce our concern that vulnerable older patients may be receiving an overdose of this one-size-fits-all drug.

To provide a typical example of what type of patient is experiencing serious side effects associated with Pradaxa, we turn to "[Dabigatran-Induced Gastrointestinal Bleeding in an Elderly Patient with Moderate Renal Impairment](#)", a case report article published online April 10, 2012 by *The Annals of Pharmacotherapy*. In relevant part, from the Abstract for this report:

**OBJECTIVE:** To report a case of dabigatran-induced overanticoagulation in a patient who developed acute renal failure and to inform health care providers of the need for appropriate patient selection and periodic monitoring of renal function in the elderly.

**CASE SUMMARY:** A 66-year-old woman treated with dabigatran for atrial fibrillation developed acute renal failure and upper gastrointestinal bleeding. She had been taking dabigatran 150 mg twice daily for 2 months, with intermittent renal insufficiency during the previous 6 months.... Her renal function never recovered and she remained hemodialysis-dependent. After a 47-day length of stay, she was transferred to a nursing home where she died 2 months later.

**DISCUSSION:** Renally eliminated drugs such as dabigatran place elderly patients at increased risk of drug accumulation and adverse drug events due to age-related decline in renal function.... In our patient, the Naranjo probability scale indicated a probable cause between the bleeding event and dabigatran use.

Our thanks to the ISMP *QuarterWatch* publication for staying on top of this Pradaxa safety story, which we will continue to follow and report on, here.

---

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>