

Pradaxa Bleeding Events: Four Major Factors Which Contributed To These Serious Side Effects

Prescriber Error, Impaired Renal Function, Patient Age, And Lack Of An Effective Reversal Agent Are Cited

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 5, 2012; see <http://bit.ly/wKfTF2>)

A Letter to The Editor, titled "[Bleeding Risk with Dabigatran in the Frail Elderly](#)" (subscription required), which appeared in the March 1, 2012 edition of the *New England Journal of Medicine (NEJM)* may help explain when and why there is a serious bleeding risk associated with Pradaxa (dabigatran).

For those without access to the original March 2012 *NEJM* Pradaxa Correspondence item, above, a nice summary of the findings is set forth in a February 29, 2012 *MedPage Today* article, "[Bleeding Risk with Blood Thinner Cited](#)":

According to the authors [Paul Harper, MD, of Palmerston North Hospital in Palmerston North, New Zealand, and colleagues], hematologists expressed concern about a possible excess of bleeding incidents with dabigatran not long after the drug became available in New Zealand in July 2011. The concern led the Hematology Society of Australia and New Zealand to form a panel to investigate.

A two-month audit of medical records revealed 78 bleeding incidents, including 44 at the three hospitals where Harper and his co-authors work. The audit identified four factors associated with bleeding complications:

- Prescriber error (including failure to allow the international normalized ratio [INR] to fall below 2.0 before starting [Pradaxa (dabigatran)], and use of the drug in patients with severe renal impairment)
- Impaired renal function
- Patient age
- Lack of an effective reversal agent for [Pradaxa (dabigatran)]

Summarizing clinical characteristics of their 44 patients, the authors noted that two-thirds were older than 80, a majority had moderate or severe renal impairment, and half had low body weight [less than 132 pounds (<60 kg)].

This same *MedPage Today* article included a response to this New Zealand letter published by the *NEJM* from the drug company responsible for Pradaxa, Boehringer-Ingelheim:

When contacted for comment by *MedPage Today*, a spokesperson for drugmaker Boehringer-Ingelheim referenced dabigatran's prescribing information, which states that the pivotal clinical trial "showed a trend toward a higher risk of major bleeding with Pradaxa 150 mg compared to warfarin in patients age 75 or older. The risk of stroke and bleeding increases with age, but the risk-benefit profile with Pradaxa 150 mg is favorable in all age groups.

"In recent months, we have provided physicians with additional guidance on the appropriate use of Pradaxa, including formal recommendations to conduct renal function testing prior to initiation of therapy and periodically as clinically indicated.

"Global data collected to date on major bleeding are consistent with our expectations based on the [pivotal] trial and are in alignment with the U.S. PI, which clearly state the benefits and risks associated with Pradaxa. Overall, the positive benefit-risk ratio of Pradaxa in nonvalvular atrial fibrillation remains unchanged."

We will continue to monitor the safety profile of Pradaxa, here, and welcome any suspected adverse reaction reports or other relevant information, which can be submitted by using the Comment link, below, or by sending us an email.

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>