



Pradaxa (dabigatran): Drug Safety Communication - Lower Risk for Stroke and Death, but Higher Risk for GI Bleeding Compared to Warfarin

[Posted 05/13/2014]

FDA最近完成一項Pradaxa (dabigatran)跟warfarin的比較研究，評估缺血或血栓性中風、腦內出血、腸胃道出血、心肌梗塞、死亡的風險。此項新研究收錄超過134,000位65歲以上的患者，研究結論：抗血液凝集的新使用患者，Pradaxa (dabigatran)造成的血栓性中風、腦內出血、死亡的風險低於warfarin；Pradaxa (dabigatran)造成腸胃道出血的風險高於使用warfarin的患者。Pradaxa和warfarin造成心肌梗塞的風險是相似的。

這項新研究相較於之前FDA上市後研究，擁有更龐大、更高齡的族群資料，並使用更複雜的分析方法去分析資料。本研究結論：除了心肌梗塞以外，研究結果與當初申請Pradaxa核准的臨床試驗結果一致。由這項結論，FDA仍認為Pradaxa有較有利的利益風險，且不需要更改藥物仿單。

建議

患者未與醫療人願討論，不應自行停止服用Pradaxa (或warfarin)。停用Pradaxa (或warfarin)可能增加中風、永久性殘疾和死亡的風險。醫療人員應依照仿單建議，開立適當的劑量。

[Posted 05/13/2014]

AUDIENCE: Cardiology, Patient, Pulmonology, Internal Medicine, Orthopedics, Neurology

ISSUE: The FDA recently completed a new study in Medicare patients comparing Pradaxa to warfarin, for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death. The new study included information from more than 134,000 Medicare patients, 65 years or older, and found that among new users of blood-thinning drugs, Pradaxa was associated with a lower risk of clot-related strokes, bleeding in the brain, and death, than warfarin. The study also found an increased risk of major gastrointestinal bleeding with use of Pradaxa as compared to warfarin. The MI risk was similar for the two drugs.

Importantly, the new study is based on a much larger and older patient population than those used in FDA's earlier review of post-market data, and employed a more sophisticated analytical method to capture and analyze the events of concern. This study's findings, except with regard to MI, are consistent with the clinical trial results that provided the basis for Pradaxa's approval. As a result of these latest findings, the FDA still considers Pradaxa to have a favorable benefit to risk profile and have made no changes to the current label or recommendations for use.

BACKGROUND: Pradaxa and warfarin are used to reduce the risk of stroke and blood clots in patients with a common type of abnormal heart rhythm called non-valvular atrial fibrillation (AF).

RECOMMENDATION: Patients should not stop taking Pradaxa (or warfarin) without first talking with their health care professionals. Stopping the use of blood-thinning medications such as Pradaxa and warfarin can increase the risk of stroke and lead to permanent disability and death. Health care professionals who prescribe Pradaxa should continue to follow the dosing recommendations in the drug label.