



The FDA Safety Information and Adverse Event Reporting Program

Pradaxa (dabigatran etexilate mesylate): Drug Safety Communication – Should Not Be Used in Patients with Mechanical Prosthetic Heart Valves

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美國FDA提醒大家，裝有機械心臟瓣膜(mechanical heart valves)之患者，不可以使用抗凝血藥品 Pradaxa (dabigatran)預防中風或預防血栓。最近有一項歐洲的臨床試驗(RE-ALIGN trial)被終止，因為裝有機械心臟瓣膜(mechanical heart valves)之患者使用Pradaxa，相較於使用warfarin的組別，發生較多之中風、心肌梗塞、血栓的事件。

Pradaxa不被核准用於心臟瓣膜問題而導致心房纖維顫動的病人。美國FDA要求裝有機械心臟瓣膜(mechanical heart valves)列為Pradaxa的禁忌症。

任何裝有機械心臟瓣膜(mechanical heart valves)且服用Pradaxa的患者，醫護人員應及時將Pradaxa換成另一種藥物。裝有生物瓣膜(bioprosthetic valves)且服用Pradaxa的患者，目前尚未評估及也無法進一步作建議。裝有人工心臟瓣膜且服用Pradaxa的患者，應該盡快跟醫療人員確定最合適的抗凝血方式。在沒有醫療人員指示下，病人不應該自行停止服用抗凝血藥物，因為可能會增加血栓事件及中風的風險。

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AUDIENCE: Cardiology, Patients

ISSUE: The U.S. Food and Drug Administration (FDA) is informing health care professionals and the public that the blood thinner (anticoagulant) Pradaxa (dabigatran etexilate mesylate) should not be used to prevent stroke or blood clots (major thromboembolic events) in patients with mechanical heart valves, also known as mechanical prosthetic heart valves. A clinical trial in Europe (the RE-ALIGN trial)¹ was recently stopped because Pradaxa users were more likely to experience strokes, heart attacks, and blood clots forming on the mechanical heart valves than were users of the anticoagulant warfarin. There was also more bleeding after valve surgery in the Pradaxa users than in the warfarin users.

Pradaxa is not approved for patients with atrial fibrillation caused by heart valve problems. FDA is requiring a contraindication (a warning against use) of Pradaxa in patients with mechanical heart valves.

BACKGROUND: Pradaxa is a blood-thinning medication used to reduce the risk of stroke and blood clots in patients with a specific condition called non-valvular atrial fibrillation (AF), a common heart rhythm abnormality that causes the upper chambers of the heart, or atria, to beat rapidly and irregularly. Pradaxa is not indicated for patients with atrial fibrillation caused by heart valve problems.

RECOMMENDATION: Health care professionals should promptly transition any patient with a mechanical heart valve who is taking Pradaxa to another medication. The use of Pradaxa in patients with another type of valve replacement made of natural biological tissue, known as a bioprosthetic valves, has not been evaluated and cannot be recommended. Patients with all types of prosthetic heart valve replacements taking Pradaxa should talk to their health care professional as soon as possible to determine the most appropriate anticoagulation treatment. Patients should not stop taking anticoagulant medications without guidance from their health care professional; stopping Pradaxa or other anticoagulants suddenly can increase the risk of blood clots and stroke.