Dabigatran

The direct thrombin inhibitor dabigatran etexilate (Pradaxa) was licensed in Ireland in March 2008 for the primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.¹ It is administered as a standard oral dose of 220 mg once daily, for a total of 10 days post-knee replacement surgery, and for 29–35 days, post-hip replacement surgery. Dabigatran replaces the use of subcutaneous low-molecular-weight heparin and works by increasing the activity of autologous antithrombin III. This licensing followed the RE-NOVATE, RE-MODEL AND RE-MOBILIZE trials, which showed that dabigatran etexilate was comparable with enoxaparin for the prevention of VTE following hip and knee arthroplasty, with similar low bleeding rates.^{2–4}

Furthermore, in April 2011, the Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive opinion on the alteration to the current licensing for dabigatran, which allows its use in “prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation.”⁵ This indication was previously approved by the United States Food and Drug Administration in October 2010. This may lead to dabigatran being licensed for use as an attractive alternative to warfarin in many patients.

Patients attending our department for diagnostic and interventional neuroradiology procedures are currently screened for use of anticoagulation medications such as aspirin, warfarin, clopidogrel, and heparin. In our practice, we have encountered patients on dabigatran therapy for both licensed and nonlicensed indications. Because its use is becoming more frequent, we would recommend also screening for dabigatran therapy before interventional procedures, to prevent bleeding complications. The manufacturers (Boehringer Ingelheim, Ingelheim am Rhein, Germany) have recommended discontinuing dabigatran at least 24 hours before “invasive or surgical procedures.” Patients with renal

impairment may require discontinuation of therapy up to 5 days before a procedure because the drug is primarily excreted renally.⁶

We think that practicing neuroradiologists should be aware of this drug as it becomes more widely available within our patient population.

References

1. European Medicines. Pradaxa, dabigatran etexilate. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000829/human_med_000981.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d124. Accessed July 20, 2011
2. Eriksson BI, Dahl OE, Rosencher N, et al. RE-MODEL Study Group. Oral dabigatran etexilate vs. subcutaneous enoxaparin for the prevention of venous thromboembolism after total knee replacement: the RE-MODEL randomized trial. *J Thromb Haemost* 2007;5:2178–85.
3. Eriksson BI, Dahl OE, Rosencher N, et al. Dabigatran etexilate versus enoxaparin for prevention of venous thromboembolism after total hip replacement: a randomized, double-blind, non-inferiority trial. *Lancet* 2007;370:949–56.
4. RE-MOBILIZE Writing Committee. Ginsberg JS, Davidson BL, Comp PC, et al. Oral thrombin inhibitor dabigatran etexilate vs North American enoxaparin regimen for prevention of venous thromboembolism after knee arthroplasty surgery. *J Arthroplasty* 2009;24:1–9.
5. European Medicines Agency. Committee for Medicinal Products for Human Use. Summary of positive opinion (post-authorisation) for Pradaxa, dabigatran etexilate mesilate. http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/000829/WC500105283.pdf. Accessed July 21, 2011
6. Boehringer Ingelheim GmbH. Pradaxa, dabigatran etexilate. Guide for surgery and interventions. <http://global.pradaxa.com/surgery-and-interventions/guide-for-surgery.html>. Accessed July 20, 2011

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