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[McMaster University](#)

New drug shows promise for those with clotting disorders: McMaster researcher

Hamilton, ON. Dec. 6, 2009 — A new study provides welcome news for patients with a common clotting disorder known as venous thromboembolism (VTE).

The condition is estimated to impact 62,000 Canadians and half-a-million Americans every year, and occurs when an abnormal clot forms in a vein and restricts the flow of blood, causing pain and swelling. In some cases, the clot may detach from its point of origin and travel through the heart to the lungs, causing a potentially fatal condition known as a pulmonary embolism.

Currently, patients with VTE are treated with a blood thinner known as warfarin, which has many burdensome interactions with other medications and foods and requires frequent monitoring of the dosage.

However, this study published today shows that an oral drug called dabigatran etexilate, which does not have these disadvantages, is as safe and effective as warfarin for combating VTE.

To compare the two drugs, an international team of researchers lead by Sam Schulman, a professor of medicine of the Michael G. DeGroot School of Medicine, who conducted a randomized, double-blind trial of 2,539 patients with acute VTE.

Today, Schulman is scheduled to present this study to the annual conference of the American Society of Hematology in New Orleans, LA, and the New England Journal of Medicine will post the study on its web site. The study will be published in the Dec. 10 edition of the New England Journal of Medicine.

For six months, roughly half of the patients in the trial (1,274) were given a fixed dose of 150 mg of dabigatran etexilate twice daily, while the other half (1,265 patients) were given warfarin once daily.

The improvement seen in both groups from the treatments was similar. After six months of treatment, only 2.4 percent of the dabigatran etexilate group (30 patients) and 2.1 percent of the warfarin group (27 patients) experienced recurrent VTE.

The safety of the two drugs was also comparable. In the dabigatran etexilate arm, 205 patients experienced bleeding (including 20 patients with major bleeding) versus 277 patients in the warfarin arm (including 24 with major bleeding). Other possible side effects, including death, acute coronary syndromes, and abnormalities in liver function tests, were infrequent in the two groups.

"We are excited by these findings and feel that they will change the standard of care for venous thromboembolism, which affects a large number of our patients," said Schulman, a physician with the thrombosis service of Hamilton Health Sciences. "This study found that dabigatran is a safe and effective anticoagulant that does not require the routine monitoring or dose adjustments that are necessary with warfarin. In other words, patients can receive the same results in a more convenient manner."

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The study was funded by Boehringer Ingelheim.

McMaster University, one of four Canadian universities listed among the Top 100 universities in the world, is renowned for its innovation in both learning and discovery. It has a student population of 23,000, and more than 140,000 alumni in 128 countries.

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