Genetic testing not cost-effective in guiding initial dosing of common blood thinner

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New analyses led by the University of Cincinnati (UC) show that genetic testing used to guide initial dosing of the blood-thinner warfarin may not be cost-effective for typical patients with atrial fibrillation but may be for patients at higher risk for major bleeding.

This study is being published in the Jan. 20, 2009, edition of *Annals of Internal Medicine*.

Warfarin is commonly prescribed to prevent blood clotting, particularly for patients with atrial fibrillation—a type of abnormal heart rhythm.

Mark Eckman, MD, professor of medicine at UC and lead investigator of the study, says the U.S. Food and Drug Administration changed the labeling for warfarin in 2007, suggesting that clinicians consider genetic testing before initiating therapy.

"There are certain genes that are known to contribute to an increased sensitivity to warfarin," he says. "The idea behind genetic testing—also known as pharmacogenetic-guided dosing— is to help guide the initial, and possibly lower, dose of warfarin for patients found to possess certain variants of the genes cytochrome P450 CYP2C9 and vitamin K epoxide reductase, or VKORC1. The hope is that more accurate dosing will translate into decreased major bleeds during the initiation phase of warfarin dosing, which is the first month or so."

Eckman says the study looked at whether the benefit of testing is worth

the costs associated with it.

Researchers first performed an analysis combining the results of the only three clinical studies published to date to determine the degree to which pharmacogenetic-guided dosing decreases the risk of major bleeds when compared with standard induction of treatment with warfarin.

The team next constructed a model to estimate the cost-effectiveness of a genotype-guided dosing strategy.

While they found that genotype-guided dosing resulted in better outcomes, it was at a relatively high cost—over $170,000 per quality-adjusted life year gained.

In other analyses, where they took into consideration the limitations of the studies, researchers found that there is only a 10 percent chance that genotype-guided dosing is likely to be cost-effective.

Researchers also looked at the impact of other variables on the cost-effectiveness of genotype-guided dosing.

Eckman says results show that genotype-guided dosing might be worth the costs if it:

-- Is used for patients at high risk for hemorrhage
-- Prevents more than 32 percent of major bleeding events
-- Is available within 24 hours
-- Costs less than $200

"This could be accomplished if testing were done in-house, at lower cost and without delays," he says, noting that currently in most cases these tests need to be sent to outside laboratories which can lead to delays in starting treatment and increased cost. "Furthermore, future studies, such

as the recently funded National Institutes of Health COAG trial, need to examine the impact of pharmacogenetic-guided dosing on bleeding risk and monitor outcomes long enough to determine the true duration of benefit."

Eckman also suggests that rather than excluding patients at higher risk for bleeding, studies should offer enrollment if it has already been determined that these patients require warfarin.

"Personalized, predictive medicine offers great promise, but we need to carefully examine the benefits and understand the cost-effectiveness of such strategies before we spend a lot of money on very expensive tests."

Source: University of Cincinnati