

Study: Gene testing helps get warfarin dose right

March 16 2010, By MARILYNN MARCHIONE, AP Medical Writer

(AP) -- Doctors are reporting an exciting win for gene testing and personalized medicine: Checking patients' DNA before starting them on a popular blood thinner helps get the tricky dose right and keep them out of the hospital.

The drug is warfarin, sold as Coumadin and in generic form. About 2 million Americans start on it each year to prevent blood clots after surgery or for other medical conditions.

However, the world's most common blood thinner is also one of its most dangerous drugs. One person's ideal dose can be 10 times that of another's. Even certain foods can throw it off.

Too much warfarin can lead to bleeding, too little can lead to clots, and either one can kill. Up to 20 percent of patients wind up in the hospital in their first six months on the drug.

Several companies sell tests for the two genes that control how warfarin is metabolized. But doctors wonder: Is it worth a \$250-to-\$400 test to guide the dose of a drug that costs less than \$6 a month?

A new study, presented Tuesday at an American College of Cardiology conference, suggests it is.

Patients given gene tests to set their initial warfarin dose had about a 30 percent lower risk of being hospitalized than similar patients whose



doses were set by trial and error.

"If we reduce just two hospitalizations per 100 patients tested, that more than compensates for the cost," said the study's leader, Dr. Robert Epstein. He is chief medical officer of Medco Health Solutions Inc., a New Jersey-based pharmacy benefits manager for many big insurance companies.

For the study, researchers at the Mayo Clinic in Rochester, Minn., did gene tests on cells from cheek swabs of 896 patients in Medco plans who were starting on warfarin. Each patient's doctor was given the results and advice on how to interpret them to set a dose.

For a comparison group, researchers selected 2,688 similar patients from the same insurance plans who also were starting on warfarin and whose initial dose was set by the doctor's best guess.

After six months, 18 percent of the gene-tested patients and 26 percent of the others had been hospitalized. That worked out to about a 30 percent lower risk for those given gene testing.

"This may help make this a safer drug to utilize," said Dr. James McClurken, chief of the cardiology conference and a heart surgeon at Temple University in Philadelphia.

Study leader Epstein said, "We've demonstrated that you can make warfarin work better with genetics."

Newer drugs seeking to compete with <u>warfarin</u> should include gene testing for dose-setting to make a fairer comparison, he said.

Medco paid for the gene tests and other study costs. Researchers from the Mayo Clinic donated their time. Results also are published in the



Journal of the American College of Cardiology.

Medco is doing another study to see whether gene testing can predict if a patient will do better on the anti-clotting drug Plavix or a competitor. On Friday, the U.S. Food and Drug Administration added its strongest warning to the label for Plavix because some patients with a gene variation cannot metabolize the drug, putting them at increased risk for heart attack and stroke.

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