

Stroke-blocking device shows promise, doctors say

March 28 2009, By MARILYNN MARCHIONE , AP Medical Writer

(AP) -- A novel device to treat a common heart problem that can lead to stroke showed promise in testing, but not without risk, new research shows.

The experimental device, called the Watchman, is the first to try to permanently fix atrial fibrillation, a heartbeat problem afflicting more than 2 million Americans. A federal [Food and Drug Administration](#) panel will consider it next month.

In the study, the Watchman was at least as good at preventing strokes as warfarin, sold as Coumadin and other brands. The drugs pose hazards of their own, so doctors and their patients are anxious for a better option.

But the procedure to implant the Watchman led to strokes in some patients, study results showed. Complications and side effects were twice as common with the device as with warfarin.

Despite those drawbacks, doctors who saw the results Saturday at the American College of Cardiology Conference were impressed.

"Wow. At first blush, this is very encouraging," and could help as many as two-thirds of those who have the heartbeat problem, said Dr. Richard Page, cardiology chief at the University of Washington in Seattle and an American Heart Association spokesman.

Atrial fibrillation occurs when the upper chambers of the heart quiver

instead of beating properly. That lets blood pool in a pouch-like appendage. Clots can form and travel to the brain, causing a [stroke](#).

The usual treatment is the anti-clotting drug warfarin, but getting the right dose is tricky - too little means a risk of stroke, and too much can cause fatal bleeding. The right amount varies by 10 times from one person to another, and even certain foods can throw it off. Patients must go to the doctor often for blood tests to monitor the dose.

The Watchman device is a fabric-covered metal cage that plugs the pouch. Doctors pass a hollow tube through a leg vein into the heart's right atrium, puncture the wall separating it from the left atrium, and implant the device through the tube.

Dr. David Holmes Jr. of the Mayo Clinic in Rochester, Minn., led a study of it in 707 patients in the United States and Europe.

After an average of 16 months of followup, there were 15 strokes and 17 deaths (from all causes) in the 463 who got the device and 11 strokes and 15 deaths in the 244 treated with warfarin, Holmes said.

The balance tipped in favor of the device. Just over 3 percent of Watchman patients suffered the main problems doctors were measuring in the trial (a composite of strokes, heart-related deaths and certain blood clots) versus 5 percent of those treated with warfarin.

About 90 percent of device patients were able to go off warfarin.

However, complications were twice as common - 8 percent in the device group and 4 percent on warfarin. Five strokes were triggered by implanting the device, and about 5 percent of device patients developed serious fluid buildup around the heart. Doctors were unable to implant the Watchman in 41 people assigned to get it.

These problems declined as the study went on, Holmes said.

Any new technology has "a learning curve" that improves with experience, said Dr. Ralph Brindis, a heart specialist at the California-based Kaiser Permanente health plan and spokesman for the college of cardiology.

The device's maker, Atritech Inc. of Plymouth, Minn., paid for the study, and Mayo may potentially receive future royalties from the device. Medicare paid \$9,500 for the procedure, including \$6,000 for the device itself, a company spokeswoman said. Hospitals typically charge two to three times the Medicare rate, she said.

Dr. Tristram Bahnon of Duke University said that if the device is approved, "patients and their physicians will have to decide whether assuming some increased risk up front is preferred to ongoing therapy with Coumadin, where there's a small risk of complications and the risk is cumulative."

For Kenneth Giunchedi, that was an easy choice. Giunchedi, 75, of suburban Chicago, had the device implanted last March by Dr. Bradley Knight of the University of Chicago Medical Center as part of the study. He had been on Coumadin for about two years.

Taking the drug was "a horrible experience for me," he said. "I was never easy to regulate - I was always in trouble. They were constantly adjusting the dosage and I would go in for a blood draw sometimes as often as three times a week. I would have done anything to get off of the Coumadin."

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