Stroke Prevention Device Misses Key Goal In Study

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The future is unclear for a promising heart device aimed at preventing strokes in people at high risk of them because of an irregular heartbeat.

Early results from a key study of Boston Scientific Corp.'s Watchman device suggested it is safer than previous testing found, but may not be better than a drug that is used now for preventing strokes, heart-related deaths and blood clots in people with atrial fibrillation over the long term.

More than 2.7 million Americans and 15 million people worldwide have atrial fibrillation. The upper chambers of the heart quiver instead of beating properly. That lets blood pool in a small pouch. Clots can form and travel to the brain, causing a stroke.

The usual treatment is blood thinners such as warfarin, sold as Coumadin and other brands. But they have problems of their own and some are very expensive. The Watchman is intended to be a permanent solution that would not require people to take medications for the rest of their lives. It's a tiny expandable umbrella that plugs the pouch, and is inserted without surgery, through a tube pushed into a vein.

A study four years ago suggested the device was at least as good at preventing strokes as warfarin is, but the procedure to implant it led to strokes in some patients. Advisers to the Food and Drug Administration narrowly recommended approving the Watchman but the federal agency required a second test of its safety and effectiveness.

The new study was to be the top presentation Saturday at an American College of Cardiology conference in San Francisco. But the group took the unprecedented step of pulling it from the program just before it was to go on because Boston Scientific released results early to investors.

The study was led by Dr. David Holmes Jr. of the Mayo Clinic in Rochester, Minn. He and the clinic have a financial stake in the device.

The study involved 407 patients — 269 assigned to get the device and 138 to get warfarin. It had three main goals, and it clearly met the first on safety — strokes, heart-related deaths, blood clots and serious complications a week after implant or release from the hospital.

"The early concerns about safety of the device ... have been alleviated," Holmes said.

The other two goals were estimated based on just 88 patients who have been tracked for 18 months after treatment. Strokes and blood clots occurred no more often with the device in those patients. However, the results suggest the device will not prove better than warfarin at 18 months on a wider measure — a combination of strokes, heart-related deaths or clots.

Whether that will be enough to win FDA approval remains to be seen. Dr. Gordon Tomaselli, a Johns Hopkins University heart specialist and former president of the American Heart Association, said he was reassured that the device seems safer, and said it might be approved just for people who cannot tolerate blood thinners long term.

"It's a mixed result," he said. "There still are complications" but fewer of them in the new study.

Dr. Hadley Wilson, cardiology chief at Carolinas HealthCare System in Charlotte, enrolled patients in the new study and predicts the FDA will require even more testing.

"It would be difficult for approvability without further study," he said.

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