Device's potential as alternative to warfarin for stroke prevention in patients with a-fib

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Vivek Y. Reddy, M.D., of the Icahn School of Medicine at Mount Sinai, New York, and colleagues examined the long-term efficacy and safety, compared to warfarin, of a device to achieve left atrial appendage closure in patients with atrial fibrillation. The study appears in the November 19 issue of *JAMA*, a cardiovascular disease theme issue.

The left atrial appendage (LAA) is a pouch-like appendix located in the upper left chamber of the heart. Studies have suggested that the LAA is the major source of clots that block blood vessels in patients with atrial fibrillation (AF). This has led to the development of mechanical approaches (via percutaneous catheters) to close the LAA. Oral anticoagulation with warfarin has been the mainstay of treatment for prevention of cardioembolic stroke in AF. Although effective, warfarin is limited by a need for lifelong coagulation monitoring and multiple medication and food interactions, according to background information in the article.

This study included 707 patients with nonvalvular AF and at least 1 additional stroke risk factor who were randomly assigned to LAA closure with a device (WATCHMAN; Boston Scientific) (n = 463) or warfarin (n = 244). The study was conducted at 59 hospitals in the U.S. and Europe.

At an average follow-up of 3.8 years, there were 39 events (stroke, systemic embolism [blood clot], and cardiovascular death) among 463 patients (8.4 percent) in the device group, compared with 34 events

among 244 patients (13.9 percent) in the warfarin group, with the difference in the event rate indicating that LAA closure met prespecified criteria for both noninferiority (not worse than) and superiority compared with warfarin. LAA closure reduced the relative risk of a composite of these events by 40 percent (1.5 percent absolute reduction) compared with warfarin anticoagulation.

Patients in the device group demonstrated lower rates of both cardiovascular death (3.7 percent vs 9.0 percent of patients) and all-cause death (12.3 percent vs 18.0 percent of patients), with the device-based strategy associated with a 60 percent relative risk reduction (1.4 percent absolute reduction) of cardiovascular death and 34 percent relative reduction (5.7 percent absolute reduction) in all-cause death. The authors note that these mortality end points are secondary end points, and due to multiplicity of data analysis, there is some uncertainty in the confidence of this conclusion.

Although the device implantation procedure was associated with early complications, the accumulation of complications related to chronic anticoagulation resulted in similar safety profiles for the two groups.

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