抗凝固療法の代替療法

PROTECT AF：新たなデバイスは心房細動患者の脳卒中リスクを軽減する

PROTECT AF: Novel device cuts stroke risk in patients with atrial fibrillation

低侵襲技術を用いた心内植込み型デバイスは非弁膜症性心房細動患者の脳卒中予防に最も広く処方されている薬剤に取って代わる可能性があるとの、心房細動患者の塞栓予防(PROTECT AF)トライアルの結果が2009年第58回American College of Cardiology学会i2サミットで発表された。研究者らは現在の標準治療であるワルファリンによる抗凝固療法と、WATCHMANとして知られる、一般的に左心耳（LAA）内に形成される血栓を捕捉する生地で覆われた膨張型ニチノールケージを比較した。707人の非弁膜症性心房細動患者を、WATCHMANデバイスでLAAを閉鎖しその後ワルファリンを中止する群（463人）またはワルファリン長期治療群（244人）に無作為に割り付けた。900超患者／年の経過観察期間中における両脳卒中（虚血および出血）発症率および心血管死－有効性の一次評価項目－はデバイス群で100患者／年当り3.4例であったのに対し、ワルファリン群では100患者／年当り5.0例であり、32%低下した（相対リスク、0.68）。

Full Text

A device implanted in the heart using minimally invasive techniques may replace the most widely prescribed drug for stroke prevention in patients with nonvalvular atrial fibrillation, according to research presented during the i2 Summit at the American College of Cardiology's 58th annual scientific session.

In the Embolic Protection in Patients with Atrial Fibrillation (PROTECT AF) trial, researchers compared the current standard of therapy, anticoagulation with warfarin, to a fabric-covered expandable nitinol cage known as the WATCHMAN, which blocks blood clots that typically form in the left atrial appendage (LAA). They found that the WATCHMAN reduced by some 30 percent the combined risk of cardiovascular death and stroke (both ischemic and hemorrhagic).

"Patients with atrial fibrillation have a six-fold increased risk of stroke and therefore require long-term anticoagulation therapy," said David R. Holmes, Jr., M.D., Scripps Professor of Medicine at the Mayo Graduate School of Medicine, Rochester, MN. "The placement of this device results in excellent long-term outcomes - effective ischemic stroke prevention with the elimination of hemorrhagic strokes and major bleeding often associated with the use of warfarin."

To implant the WATCHMAN, an interventional cardiologist guides the device into the right atrium, then into the left atrium through a puncture in the wall separating the two upper chambers of the heart. Once the catheter is positioned in the opening of LAA, the WATCHMAN is released and left permanently in place to block the formation and release of blood clots.

For the PROTECT AF study, 707 patients with nonvalvular atrial fibrillation were randomly assigned to closure of the LAA with the WATCHMAN device (463 patients), followed by discontinuation of warfarin, or to long-term treatment with warfarin (244 patients). The study found in over 900 patient-years of follow-up that the combined rate of stroke (ischemic and hemorrhagic) and cardiovascular death - the primary measures of effectiveness - was 3.4 per 100 patient-years in the device group vs. 5.0 per 100 patient-years in the warfarin group, a reduction of 32 percent (relative risk [RR], 0.68).

As for the safety of the device, the researchers observed more procedure-related complications in patients treated with the device (8.7 vs. 4.2 per 100 patient-years; RR, 2.08). Most complications were related to device implantation. However, after successful implantation of the WATCHMAN and discontinuation of warfarin therapy, complication rates were significantly lower with device therapy (1.7 vs. 4.2 per 100 patient-years; RR, 0.40).

The researchers concluded that the WATCHMAN is an effective alternative to warfarin therapy for preventing stroke in patients with atrial fibrillation.

"The take-home message is that although there are complications associated with implantation of the device, patients can avoid the need for chronic warfarin therapy, with all its attendant risks," Holmes said.