心房細動に対してアブレーションは薬物よりも優れている

STOP-AF and CABANA：トライアルの結果、心房細動に対しては薬物治療よりもアブレーションの方が有効であることが示された

STOP-AF and CABANA: Trials show effectiveness of ablation techniques over anti-arrhythmic drug therapy for the treatment of atrial fibrillation

第59回American College of Cardiology学会で発表された2つのスタディの結果、心房細動（AF）の治療としてアブレーションは抗不整脈薬治療よりも有効であり安全性は同等であることが示された。26の医療機関の患者245人を組み入れた発作性心房細動の維持治療（The Sustained Treatment of Paroxysmal Atrial Fibrillation：STOP-AF）スタディでは、Arctic Front®心臓クリオアブレーションカテーテルシステムで治療された発作性AF患者の70%近くが施術後1年間洞調律を維持し、一方薬物療法群で洞調律を維持できたのは7%を少し上回っただけであった。クリオアブレーションの初期成功率は98%であった。より実質的な心血管疾患を基礎疾患として有するより進行したAF患者に対するカテーテルアブレーションの有効性を評価した初めてのスタディのひとつである、心房細動に対するカテーテルアブレーションと抗不整脈薬治療の比較（The Catheter Ablation Versus Anti-arrhythmic Drug Therapy for Atrial Fibrillation：CABANA）パイロット研究の結果、カテーテルアブレーションは薬物療法よりも症候性AF再発予防に有効であることが示された。しかし、持続性および長期の持続性AF患者も含むこれらの患者らにおける成功率は他の無作為化臨床試験で認められた成功率よりも低かった。CABANAは大規模無作為化コントロール試験の基礎を築くようにデザインされた。

Full Text

In patients with an intermittent form of atrial fibrillation, use of a cryoablation catheter is nearly 10 times more effective and equally safe as conventional anti-arrhythmic drug therapy for eliminating the irregular heart rhythm, according to research presented at the American College of Cardiology's 59th annual scientific session. Another study, also presented at the ACC2010, showed that using an ablation catheter appears to be more effective than anti-arrhythmic therapy in treating more advanced atrial fibrillation.

The Sustained Treatment of Paroxysmal Atrial Fibrillation (STOP-AF) study found that nearly 70 percent of patients with intermittent, or paroxysmal, atrial fibrillation who were treated with the Arctic Front® Cardiac CryoAblation Catheter System remained free of atrial fibrillation after one year, as compared with just over 7 percent of patients assigned to drug therapy.

For the study, investigators from 26 medical centers in the United States and Canada recruited 245 patients with paroxysmal atrial fibrillation. All patients had already tried treatment with at least one antiarrhythmic drug, but were unsuccessful. Patients were randomly assigned in a 2-to-1 ratio to cryoablation or treatment with an anti-arrhythmic medication that had not previously failed. During the next 90 days data collection was deferred, allowing each patient's doctor to adjust drug therapy or repeat cryoablation, as needed. After that, patients were followed-up in the clinic at 1, 3, 6, 9 and 12 months. They also sent heart-rhythm tracings to their doctor over telephone lines every week and when experiencing symptoms.

Researchers found that the cryoablation procedure was initially successful in about 98 percent of patients.

After one year, nearly 70 percent of patients treated with cryoablation were free of atrial fibrillation and had not required use of a non-study drug or an interventional procedure to treat atrial fibrillation, as compared with just 7 percent of patients in the anti-arrhythmic drug group.

Just over 3 percent of patients treated with cryoablation experienced a serious complication, specifically, narrowing of the pulmonary vein in seven out of 228 patients, one of whom required an interventional procedure to widen the vein. Phrenic nerve palsy was noted after 11 percent of cryoablation procedures, but none of the cases was considered serious, and approximately 98 percent resolved by the 12-month follow up.

Researchers also tracked complications related to atrial fibrillation itself. During the follow-up period, nearly 97 percent of patients in the cryoablation group and nearly 92 percent of patients in the drug therapy group avoided cardiovascular death, myocardial infarction, stroke, or hospitalization for recurrence or ablation of atrial fibrillation, ablation of atrial flutter, complications related to unwanted blood clots, heart failure, hemorrhage, or anti-arrhythmic drug treatment. Less than 1 percent of patients treated with cryoablation were hospitalized for the recurrence of atrial fibrillation, as compared with 6 percent in the anti-arrhythmic drug group.

The Catheter Ablation Versus Anti-arrhythmic Drug Therapy for Atrial Fibrillation (CABANA) pilot study-one of the first to evaluate the feasibility of catheter ablation in patients with more advanced atrial fibrillation and substantial underlying cardiovascular disease-was designed to lay the foundation for a large, randomized controlled trial.

"This pilot study establishes the feasibility and importance of conducting an extended pivotal trial critical for establishing long-term outcomes, mortality, quality of life, and cost of ablation and drug therapy for atrial fibrillation," said Douglas L. Packer, M.D., a cardiologist at Mayo Clinic, Rochester, MN and trial principal investigator.

Abnormal electrical impulses cause the upper chambers of the heart to quiver, and stimulate the heart to race at a rapid rate, rather than contract with a slow, steady rhythm. Anti-arrhythmic drugs are successful in eliminating atrial fibrillation in only about half of patients and can have serious side effects. Drug therapy is often aimed at simply controlling the heart rate. Catheter ablation is an alternative treatment in which a catheter is threaded into the left atrium and typically radiofrequency energy is applied to tissue around the entrance to the pulmonary veins, where most abnormal electrical impulses originate, as well as other trouble spots in the heart.

For the study, investigators recruited 60 patients with atrial fibrillation, more than two-thirds of whom had a persistent or long-standing persistent form of the arrhythmia. The study group tended to have multiple additional health problems: 80 percent of patients had high blood pressure, 18 percent had diabetes, 35 percent had coronary artery disease, and 36 percent had mild-to-moderate heart failure. Nearly half (48 percent) already had left atrial enlargement. Some 30 percent of patients had previously tried anti-arrhythmic drug therapy.

Of the 60 patients in the study, 31 were randomly assigned to drug therapy, and were treated with either anti-arrhythmic drugs (87 percent) or medications to control the heart rate only without eliminating the arrhythmia (13 percent). The remaining 29 patients were randomly assigned to catheter ablation. In nearly all patients, radiofrequency energy was applied to tissue around the entrance of the pulmonary veins. In addition, in 13 out of 29 patients (45 percent) electrophysiologists chose to create additional linear lesions to block the spread of electrical impulses in problem areas.

Investigators found that catheter ablation was more effective than drug therapy for preventing recurrent symptomatic atrial fibrillation. However, treatment success rates in these patients, some of whom had persistent and long-standing persistent atrial fibrillation, were lower than observed in other randomized clinical trials. Late recurrent atrial fibrillation may also diminish the overall effectiveness of ablation therapy, according to Dr. Packer. The CABANA pivotal trial, which will further examine these issues, is currently recruiting patients and is aiming for a total enrollment of 3,000.
The STOP-AF study was funded by Medtronic.

The CABANA Pilot study was funded by St. Jude Medical Foundation.

Dr. Packer in the past 12 months has provided consulting services for Biosense Webster, Inc., Boston Scientific, CyberHeart, Medtronic, Inc., nContact, Sanofi-Aventis, St. Jude Medical, and Toray Industries. Dr. Packer received no personal compensation for these consulting activities. Dr. Packer receives research funding from the NIH, Medtronic, Inc., CryoCath, Siemens AG, EP Limited, Minnesota Partnership for Biotechnology and Medical Genomics/ University of Minnesota, Biosense Webster, Inc. and Boston Scientific.

Mayo Clinic and Drs. Packer and Robb have a financial interest in mapping technology that may have been used at some of the 10 centers participating in this pilot research. In accordance with the Bayh-Dole Act, this technology has been licensed to St. Jude Medical, and Mayo Clinic and Drs. Packer and Robb have received annual royalties greater than $10,000, the federal threshold for significant financial interest.

Mayo Clinic and Dr. Robb have a financial interest in Analyze-AVW technology that was used to analyze some of the heart images in this research. In accordance with the Bayh-Dole Act, this technology has been licensed to commercial entities, and both Mayo Clinic and Dr. Robb have received royalties greater than $10,000, the federal threshold for significant financial interest. In addition, Mayo Clinic holds an equity position in the company to which the AVW technology has been licensed.

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