

Cryoablation Trial Studies Arrhythmia Treatment Option

February 2, 2005

Jeffrey Itrich

Gregory Feld, M.D., Medical Director of the UCSD Electrophysiology Program has embarked on the final phase of a research study comparing a freezing technique that changes the heart's rhythm to standard medication therapy to treat a common heart condition called atrial fibrillation.

Atrial fibrillation is a type of irregular heartbeat, or arrhythmia, characterized by rapid beating throughout the heart's atrium. The American Heart Association estimates that approximately 2 million people in the U.S. suffer from atrial fibrillation, the most common cardiac arrhythmia. Of the 750,000 strokes that occur annually, about 15 percent occur in atrial fibrillation patients when a blood clot leaves the heart and lodges in a brain artery. Anti-arrhythmia medications are the current standard medical therapy for treating atrial fibrillation, but Feld says they are effective only half the time.

Patients can also be treated with radiofrequency ablation, a technique that cauterizes the heart tissue that causes the electrophysiologic disturbance. The "burning" of tissue can lead to serious side effects, however.

Cryoablation is a freezing technique that employs single-use, cold-tip cardiac catheters that can freeze to minus 80 degrees. The tool is used to selectively create lesions in the heart to interrupt the electrical conductivity that causes arrhythmias without destroying surrounding heart tissue.

The research trial will recruit 165-200 patients nationwide at 20 centers who suffer from erratic atrial fibrillation, which comes and goes on its own. Feld, director of the study, plans to enroll 20 patients at the UCSD Medical Center site. Half the patients will be randomized to anti-arrhythmic drugs and half to cryoablation.

"The medication group will be followed on antiarrhythmic drugs," says Feld. "The other half will go to the laboratory for their ablation. Both groups of patients will be followed for 12 months, but if the patients in the medication group have a recurrence of atrial fibrillation they can cross over and have the ablation after three months."

At the end of the study Feld anticipates that most of the patients who were randomized to drug therapy will have a recurrence and cross over to have ablation. He bases this belief on the fact that the patients fail anti-arrhythmic medications more than 50% of the time.

Feld estimates that up to 10% of the population has atrial fibrillation by age 80 and three to five percent develop it by age 60.

The patented cryoablation system is approved in Europe where physicians use it to treat atrial fibrillation, atrial flutter and supraventricular tachycardia. Over 600 patients have been treated worldwide to date with a 98% overall acute treatment success rate.

CryoCor, Inc., of San Diego, manufacturer of the cryoablation system anticipates the investigational device will be on the market in the next 24 months if research continues to proceed as expected.

Media Contact: Jeffree Itrich (619) 543-6163