
MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWSPAPER

TUESDAY, MAY 19, 2009

VOL. 13, No. 95

PAGE 1 OF 11

Heart Rhythm Society

Atrial fibrillation: progress, but many unresolved issues

By LARRY HAIMOVITCH

Medical Device Daily Contributing Writer BOSTON – The 30th annual scientific sessions of the Heart Rhythm Society (HRS; Washington) took place here last week, with record attendance as the field of electrophysiology (EP) continues to ascend in importance in the healthcare world.

For the third consecutive year, HRS sponsored a two day “AF Summit,” which once again drew an overflow attendance and was chock full of the latest clinical data on this emerging field.

The importance of atrial fibrillation (AF) to the EP community cannot be overestimated. It is by far the most common arrhythmia treated and clearly is an area with the greatest opportunity to improve patient outcomes, yet remains incredibly frustrating because there are so many

unanswered questions. This was exemplified by the title of one panel discussion, “Are We Better off than Four Years Ago: What is the Best Approach?”

The rising awareness of AF can be seen by the recent introduction of House Resolution 255, which called for a National Atrial Fibrillation Awareness Month in September 2009. In strongly supporting this initiative, Mark Estes III, MD, president of the HRS said that “currently less than 30% of AF patients receive the recommended treatment. Therefore, an AF Awareness Month will play an important role in not only raising awareness but also improving patient care and ultimately saving lives.”

With the average age of an AF patient exceeding 70 years of age and a rapidly aging global population, several speakers cautioned that AF could soon become an “epidemic.” Several experts have predicted that between now and 2050, the prevalence or pool of AF patients will nearly triple.

With the success rate of anti-arrhythmic drugs widely estimated at well below 50%, catheter ablation of atrial fibrillation has become a very important weapon in the EP’s armamentarium. There were no FDA-approved products in the category until late-February, when Biosense Webster (Diamond Bar, California), a Johnson & Johnson (New Brunswick, New Jersey) company attained clearance for its Navistar Thermocool catheter. Despite the absence of approved devices, domestic AF ablations have approximately doubled in the past three to four years and are estimated at about 75,000 to 80,000 in the U.S. this year.

During a session titled “Critical Issues in AF Therapy” several speakers noted that the results of catheter ablation are improving but yet have room for much more improvement. For myriad reasons, the true “success rate” is difficult to pinpoint and far more significantly, the measures of success vary widely. This aspect was noted by several speakers, one who succinctly said “there is so much more truth to find out.”

One consensus that has clearly emerged is that ablation of the pulmonary veins (PVs) is, in the words of Pierre Jais, MD, Haut-Leveque Hospital (Bordeaux Pessac, France), the “cornerstone” of catheter ablation. Jais said that is especially true for a paroxysmal (intermittent, typically early stage) AF. In addition, it is generally accepted that PV ablation using a standard point-to-point radio frequency (RF) catheter ablation is limited by the technical challenges of maintaining catheter stability and all too often results in the recurrence of AF due to the lack of lesion continuity.

There are several unresolved issues in the catheter ablation of the PVs: Two key ones are 1) What other areas of the heart need to be ablated to halt the AF; 2) Are there other approaches or energy sources that will buoy the results of PV ablation or isolation. With regards to the first question, several speakers discussed in detail other ablation sites such as the ganglionic plexi (GPs or the autonomic nervous system) and complex fractionated atrial electrograms (CFAEs). With the modest success of PV

ablation alone, these two ablation sites are gaining favor in the EP community and in many institutions are becoming the standard of care in AF ablation.

More importantly, the clinical results from adding these additional ablation strategies are positive. According to Warren Jackman, MD, of the University of Oklahoma Health Science Center (Oklahoma City), the addition of GPs to an AF ablation can boost the success rate up to an additional 20%. However, this strategy adds to an already long and complex procedure.

According to D. Wyn Davies, MD, St. Mary's Hospital (London, UK), the goal of AF ablation ideally should be a "single shot," which he discussed in a comprehensive talk on non-radio frequency energy sources such as cryothermia, laser, high intensity focused ultrasound, irreversible electroporation and others.

A single shot of energy in each PV, which ideally would create complete block of the AF, could also simplify and shorten the procedure. The most commercially advanced of these devices is the CryoCath Arctic Front cryo balloon, which has already been commercialized in Europe and is expected to report results of its U.S. prospective randomized controlled pivotal trial in the U.S. in 2H09. As previously reported (*Medical Device Daily*, Dec. 22, 2008), Medtronic (Minneapolis) recently placed a big bet on single shot cryo PV ablation, purchasing CryoCath for nearly \$400 million.

An intriguing player in this space is CardioFocus (Marlborough, Massachusetts), whose tagline at its HRS exhibit was "See what you ablate, ablate what you see." This slogan refers to the unique and very useful capability of its catheter to view the ablation zone in the PVs in real-time with direct endoscopic visualization. In addition, cases have been performed, demonstrating direct lesion visualization in real-time.

Physicians who have seen both aspects of this visualization capability believe that it represents a huge advantage over traditional fluoroscopic imaging and also better than intracardiac echocardiography (ICE). It is the only ablation catheter that has this attribute.

An equally if not more important aspect of the company's device is that its balloon, which delivers ablative laser energy at 980 nm, is "compliant," that is, it is soft and will fit into the hugely different shapes and sizes of the patient's pulmonary veins. In contrast, the CryoCath Arctic Front balloon is rigid and while it comes in two different sizes, will not fit well into all PVs. A non-compliant balloon may result in incomplete ablation in the PVs and allow for recurrence of the AF.

Although its clinical data is limited to 18 patients treated since early 2009, it appears very promising, with a 95% success rate in chronic isolation at three months postprocedure. In addition, there were no clinical recurrences or adverse events. The success rate compares very favorably to 63% reported in the pivotal trial with the Thermocool catheter. The latter required using multiple procedures.

Vivek Reddy, MD, director of cardiac electrophysiology at the University of Miami Miller School of Medicine (Miami) presented initial data on this catheter at the Scripps Clinic (La Jolla, California) "Percutaneous Catheter Ablation of Atrial Fibrillation" conference in March (*MDD*, March 11, 2009) and noted that the early human data from cases being performed at Homolka Hospital (Prague) was very encouraging. In an interview with *MDD* at HRS, Reddy said "this is by far the most promising technology I have seen for AF catheter ablation. I really like both the direct visualization and the fully compliant balloon and I think it could ultimately be the big winner in this market."

The company, which has been venture capital-backed for several years, is seeking to gain CE mark approval in the coming months and anticipates initiating a human clinical trial in 2009 in the U.S. ■