Cryoballoon ablation for atrial fibrillation. Is it the right choice for my practice?

“Even if you’re on the right track, you’ll get run over if you just sit there.”
— Will Rogers

Radiofrequency catheter ablation is an established approach for medically refractive atrial fibrillation (AF). However, success rates are far from 100% and complications of untoward thermal injury persist. Cryoballoon ablation is an exciting novel technique to perform pulmonary vein isolation in these patients. The refinement and availability of this tool reflect a committed effort to enhance the safety and efficacy of percutaneous catheter ablation. With the emergence of any new technology there often is enthusiasm that the new device may overcome or minimize current limitations. Simultaneously, there is a nostalgia concerning older tools that are familiar and understood that can conceal potential advantages of implementing the new technology.

In addition to economical considerations that can be significant, operators must ask 3 fundamental questions before implementing a new technology. First, will the technology increase the success of my procedures? Next, will the technology improve procedural safety? Finally, will the tool make me more efficient in a health care environment with declining reimbursements that are often offset by attempting to increase productivity? In this issue of Innovations in Cardiac Rhythm Management, Kühne and Sticherling provide a comprehensive review of cryoballoon ablation to assist in answering these fundamental questions about new technology implementation. They highlight very nicely many of the advantages and challenges associated with cryoballoon ablation.

What can we expect regarding acute and long-term procedural efficacy with cryoballoon ablation? Recently the STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) clinic trial was presented at the American College of Cardiology Annual Scientific Sessions. Pulmonary vein isolation was achieved in 98.2 percent (160/163) of cryoblation patients. Excluding a 3 month blanking period, at 12 months, 69.9 percent of cryoablation patients (60.1% with a single ablation) were free of AF and off antiarrhythmic drugs (http://assets.cardiosource.com/packer_stop_af1.ppt, accessed March 21, 2011). In a recently updated worldwide survey of outcomes after radiofrequency ablation for AF, 10,488 of 16,309 patients (median, 70.0%; interquartile range, 57.7–75.4%) were asymptomatic without antiarrhythmic drugs over 18 (range, 3–24) months of follow-up.1 A gross comparison of these outcomes across multiple operators suggests that cryoballoon ablation is effective. However, as with any procedure, the prior volume performed impacts contemporary outcomes. At the 2011 Boston AF symposium, Dr. Jeremy Ruskin presented outcomes based upon learning curve (http://www.medpagetoday.com/MeetingCoverage/HRS/20130, accessed March 22, 2011). In physicians who had performed 12–23 cryoablation procedures success rates were 90% compared to 56% for those who had performed only one or two cases (on average a 9% increase in the odds of success with each additional procedure performed).

Next, will cryoballoon ablation impact safety favorably? In the STOP AF there were no esophageal injuries. Seven patients (4.3%) experienced a stroke (2.5%) or transient ischemic attack (1.8%), 5 (3.1%) pulmonary vein stenosis, and 1 tamponade. In the updated worldwide survey, 0.9% experienced a stroke or transient ischemic attack, 0.29% pulmonary vein stenosis, and 1.3% tamponade. On the surface complications in the STOP-AF trial are higher, but these were collected in the context of a clinical trial in which follow-up is routine and these adverse endpoints are actively sought and quantified. Nonetheless, endpoints that are clinically apparent independent of a study environment such as tamponade and stroke can be used to compare procedural safety. In this regard, stroke rates were slightly higher than expected with cryoballoon ablation and this complication will need to be carefully followed with use of this technology to see if procedural modifications and experience can reduce the rate. In addition to these endpoints, somewhat unique to balloon-based therapies in a higher risk of phrenic nerve paralysis. In STOP-AF, phrenic nerve paralysis occurred in 29 patients treated with cryoablation. The paralysis resolved at 12 months in 25 patients. One of the 4 patients with persistent phrenic nerve paralysis had symptoms. Phrenic nerve paralysis risk should decrease with operator experience. Inflation of balloons distorts the right superior pulmonary vein and phrenic nerve anatomical structures.
relationship. This can be minimized by not pushing the balloon into the right superior pulmonary vein as well as pacing the nerve during energy delivery as a means to detect early, and often reversible, injury. Although often subclinical, phrenic nerve injury is not always benign. In patients with preexisting lung disease it can be debilitating. Since respiratory failure can be a serious complication of catheter ablation, efforts to minimize complications that can impact respiratory function are necessary. Finally, can this technology decrease risk of esophageal injury. With cryothermal ablation, the esophagus can be significantly cooled in animal models. Fortunately, only minor tissue disruption is seen with direct cooling with no significant chronic disruptive tissue damage. Although the exact risk to the esophagus will not be known until this tool is applied broadly in clinical practice, the animal models are encouraging that this devastating complication may be minimized.

Finally, can this technology improve clinical volumes and catheterization work environment flow by decreasing procedural times? As with any new technology there is an anticipated learning curve that will impact an early understanding of procedure time. Nonetheless, in the STOP-AF trial there was a broad range of experience with the technology which likely will approximate procedure patterns when applied broadly in diverse clinical settings and with multiple operators. In this trial the mean procedural duration was 371 (range 200–650) minutes with 62.8 (range 8–229) minutes of fluoroscopy exposure. In the subanalysis of operator experience presented at the 2011 Boston AF symposium, experience with the cyroballoon reduced procedure time by 15% and fluoroscopy time by 24% compared to first-time users. These procedural times, particularly with experience, compare to those achieved with radiofrequency ablation. Although the fluoroscopy times were on average high, the low time of 8 minutes demonstrates the potential utility of this device with experience and appropriate patient selection.

Will Rogers once said “Good judgment comes from experience, and a lot of that comes from bad judgment”. Our good and bad past and current experiences will continue to provide incentive to improve procedural techniques and disease treatments. Cryoballoon systems are effective and relatively safe. These systems, as well as radiofrequency-based tools, still leave ample margin for improvements to enhance long-term therapy efficacy and safety. These improvements will be necessary to treat an aging population that is living longer with cardiovascular disease. Operators should consider use of cryoballoon technologies if fundamentally it makes sense in regards to anticipated efficacy, safety, and economically in their unique situations.

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References