# Benefits of an Early Cryoablation Approach for Atrial Fibrillation

## Interview With Denise M. Sorrentino, MD, FACC, FHRS

*Interview by Jodie Elrod*

**Denise M. Sorrentino, MD, FACC, FHRS**

In this interview, *EP Lab Digest* features an interview with Dr. Denise Sorrentino from Iowa Heart Center in Des Moines, Iowa, about her use of cryoablation and work with the prospective, multicenter randomized study, STOP AF First.

**What would you say is the most significant aspect of the recent clinical evidence that has been published on cryoablation as an initial rhythm control strategy?**

It's critical information for patients having their first atrial fibrillation (AF) event and visiting their primary care physician, because the sooner we can get to a procedure that will eliminate those triggers in the heart, the better these patients will do in both the short and long term.

I always tell my patients that while we have many treatments for AF, we do not have a cure. As an electrophysiologist that has been in practice for 25 years, our medications have gone nowhere. The annual success rates of AF medications are in the 60%-70% range at best, and patients have symptoms, side effects, and breakthrough arrhythmias. Therefore, directly treating the pulmonary vein (PV) triggers is so important. AF ablation with the Arctic Front™ (Medtronic) cryoballoon technology is effective and has been in use now for over a decade in the U.S.

However, we're not only talking about PV triggers in the heart. Other risk factors for AF include high blood pressure, poorly controlled diabetes, untreated or poorly treated sleep apnea, elevated body mass index (BMI), and coronary or valvular heart disease, especially mitral valvular heart disease. I let my patients know that AF is a very personalized diagnosis and it is different for everybody. My patients always want to tell me about their elderly neighbor or their younger son in his early 30s who had an AF ablation. In my practice, I have both 19-year-old and 90-year-old patients with AF. A lot of my patients, even in their 30s, 40s, and 50s, have other risk factors that need to be addressed before their risk of AF recurrence can be determined. Data from the STOP AF First trial, which demonstrated the low risk of cryoablation as a first-line treatment, has really helped a lot of these patients stay away from antiarrhythmic drugs and restore their sinus rhythm so they can work on other comorbidities.

**You were involved in the STOP AF First trial. Why was it important to you to participate in this trial?**

For electrophysiologists, the real problem is that we're seeing AF patients too late in their treatment. Meaning, when a patient has AF, they start with a visit to their primary care physician and are often placed on a beta blocker or calcium channel blocker. When they have more AF, they visit a cardiologist, and while general cardiologists do an excellent job, the patient is often put on a direct oral anticoagulant or warfarin or antiarrhythmic, and maybe a cardioversion is performed, and the patient follows up with them. The patient then has another episode of AF, so maybe they have another cardioversion or try another antiarrhythmic. By the time they see me, I often will be reviewing well over 80 to 100 pages of outside records to outline all of their AF events and treatments.

As electrophysiologists, we know that eliminating PV triggers early on helps save patients from this rotating door of antiarrhythmic drugs, calcium channel blockers, beta blockers, direct oral anticoagulants, and cardioversions. So, it was important to participate in this trial because we were randomizing patients to an antiarrhythmic vs PV ablation using the Arctic Front Advance Cryoablation Catheter.

It's critical this information gets out to ER and urgent care physicians as well, so patients can be

**Figure 1.** Arctic Front™ (Medtronic) cryoballoon.

treated earlier instead of waiting until the disease has progressed to persistent or long-standing persistent AF. I have even seen what I would classify as permanent AF patients, who have had AF for three to five years and who are then referred for an ablation; literature demonstrated AF progression to this degree shows little success with AF ablation.

**Many EPs wouldn't disagree that earlier treatment with catheter ablation is important, but both patients and referring physicians may have a different perspective. What would you say to them?**

I would recommend they simply look at the data and conclusions from the STOP AF First trial, or even the recent meta-analysis that reviewed all three randomized trials that used ablation with the cryoballoon as first-line treatment, and then come in for a consult. As a specialist, I often see patients who need to be referred for other invasive procedures such as bypass surgery or a transcatheter aortic valve replacement (TAVR). These patients are generally afraid or concerned when they first learn about these procedures, and so I always tell them to get an initial consult from the person doing the procedure.

In my clinic, I spend a lot of time talking about procedures in depth, including risks, benefits, and alternatives. The Arctic Front cryoballoon technology has been available for over 10 years in the U.S. and over 16 years globally. The risks of this ablation procedure are relatively low, the potential benefits are high, and the alternative (medication) also has risks and potentially not the same long-term benefits. Getting in and out is very safe and efficient; I personally use less sheaths and catheters. We also now use a vein closure device that allows for same-day discharge two and a half hours after the procedure. Especially during a pandemic, I think it's helpful to have a procedure that can be safely done without hospital admission, achieve significant reduction in AF burden, and help the patient stay off antiarrhythmics.

Figure 2. **Photo from an Arctic Front case.**

So again, find an electrophysiologist who is doing the procedure, discuss the procedure, and then make a decision. The more data that people have access to, the better. In 2021, patients are well-educated consumers — everyone goes online to learn about new advancements, and I believe people are more open-minded as well. For the most part, we're doing better with patient education. I give patients teaching booklets and describe their procedure using a three-dimensional heart model. Education is the key to understanding.

**What have you seen from the results of both an early cryoablation approach vs an early radiofrequency (RF) approach? What have you seen with patient outcomes? How do you approach these two differing ways of treatment with patients, and what do you look for?**

When I first started doing AF ablations in approximately 2005, there was no cryoballoon, so I was only using RF. My procedure time was double what it is now. For someone who is extremely efficient with RF ablation, it probably doesn't take that long, but these were the old days. Back then, I would do a double transseptal approach, so that is two pokes to enter from the right atrium to the left instead of one. In the early days, I would also do wide area circumferential ablation (WACA) using an older-generation mapping system to mark our points, and there were always little adjustments. There is always that risk with that approach, and I still see it in 2021. When I see patients who have had focal point RF ablation, there is often a gap in the line and a recurrence of left atrial flutter, which then needs to be ablated.

Once I'm done with an ablation using the Arctic Front balloon technology, I check the vein and antrum, and there are no gaps or lines. I'm not saying it's 100% or that you cannot have recurrent AF, but, in my practice, a gap does not occur and there is a zero to very low recurrence of left atrial flutter. In addition, the current technology allows for a shorter procedure and the patient to be under anesthesia for a shorter period of time. I still use different technologies to confirm I have occlusion, that there is no dropping temperature for the esophagus, no phrenic nerve injury, and the vein has entrance and exit block. It's not like I go in there, freeze the veins, and get out. I'm still using all these parameters to make sure the outcome is excellent.

So for operators who have used cryo for a long period of time, I think these procedures can be done more quickly and safely than RF. But I'm not trying to put down RF ablation — I still use RF for other types of ablations that I do. There are also some people who have only used RF since 2005, and they're safe and efficient with their approach.

**Why and how have you educated patients about earlier treatment with catheter ablation vs antiarrhythmic drugs? What do you find is most important to patients when discussing treatment options for their AF?**

I think a two-way conversation that ensures clarity is most important. The old model of the patient-doctor relationship was not good. It was one sided, in which the doctor said to the patient, "This is what you have to do," and the patient would then go home and tell their family, "This is what I'm being told I have to do." I think some of my patients still want that, but I refuse to do it. I make a recommendation on what I think they should do based on a certain level of outcome, and then I present options A, B, C, and all the way down the alphabet. We never have a one-option situation, especially with AF.

Sal Khan from the Khan Academy spoke about a linear learning model at the 2016 Heart Rhythm Society Scientific Sessions. At the Khan Academy, a student cannot move on to the next level until they have proven they understand the first level. Patients can benefit from this type of linear learning approach as well. When we start talking about the heart with patients, we sometimes need to start with the basics. That is why I go into every patient visit with a heart model, because for patients to make an informed decision about their medical diagnosis, they really do need to understand what is happening. I don't mean we're going to provide them all with a medical school level of education — patients do not need to know about the subtleties of a PV potential. But we need to have a conversation with patients about what is going on and why, how it can be treated, and what that looks like. Educating people in a 15-minute office visit is not enough.

I ask each of my patients the day of their procedure, "We spoke about this before, but do you have any other questions?" I want to know they understand what we're doing. It's so hard to go through with or sign a consent for a medical procedure otherwise. My goal is to improve patient education, giving as many talks and grand rounds as I can. One hospital where I do grand rounds has posted video recordings of my AF and atrial flutter presentations on YouTube, and as a result, I've heard from patients from all over wanting to know more. What this means is that patients aren't getting all the answers or education they need. Therefore, we need to make sure the information starts out very basic and moves onward from there.

**What has been your most valuable lesson about the patient care pathway when it comes to AF and how patients are taking control of and managing their own care?**

If my patient goes to zero AF two months after the ablation, I still see them in follow-up and we do a monitor; if they're having no symptoms, I stop their antiarrhythmic and direct oral anticoagulants. When I see them again in six months and they're doing great, we see them again in a year, and then another year, and then every two years. But even if they say, "I'm not having AF anymore" at that time, they can still have AF in the future.

It's important to understand that AF is a multifactorial disease and it's chronic. For example, even if a patient who used to have high blood pressure now has it under control through a managed diet and weight loss, they still have the propensity for

Figure 3. Dr. Sorrentino with the members of the MercyOne Des Moines EP team.

high blood pressure. If their eating habits, BMI, or other factors in life were to change, they would be at increased risk again for having high blood pressure. So for those patients, I still have them check their blood pressure on a weekly basis. AF is not a one and done diagnosis. If we do an ablation on a patient at age 19 and they have no other risk factors, I cannot guarantee at age 40 that they won't be 25 pounds heavier and an early type 2 diabetic.

The patient care path is multifactorial. I tell patients that I get to do the easy part, which is eliminating PV potentials. They have to do the hard part, which is to focus on managing their high blood pressure, diabetes, or BMI. When a patient has a better understanding of AF, it reduces the risk of them coming back and saying, "Your ablation didn't work, I still have AF." I often have to tell patients that if we don't address this as a multifactorial disease, we shouldn't even consider an ablation, because they'll be disappointed with the outcome. I've been in practice long enough to know that if other risk factors aren't addressed, the patient will be back. However, if they are addressed early, we can have better long-term results.

**What are some examples of partnerships with referring cardiologists that have been successful? Why would you say so?**

I'm with a large group that is hospital affiliated. In my practice, we currently have 66 physicians. Some of those are cardiothoracic surgeons, some are vascular surgeons, many are general cardiologists, and others are subspecialties such as imaging, advanced heart failure, structural heart, and interventional. We hold physician meetings twice quarterly, and it's a great forum for education, because I can learn from my structural heart colleagues about the new data on TAVR and when patients should be referred. I can then immediately refer my patients to those colleagues who will take care of them. So fortunately, I have a built-in referral base in my practice, and that has been very successful. I'm not saying every general cardiologist sends me patients early. Sometimes they'll first try a few antiarrhythmics or cardioversions. So we're not completely there yet, and we could certainly be talking about STOP AF First.

My biggest challenge is with referring physicians outside my practice. There are three cardiologists from another local practice that I'm collegial with, but we're also competitors. I need to talk with them specifically about STOP AF First, because of the referrals I'm receiving from them, I'm often seeing these patients last. Some of their patients have been having AF since before 2010. However, during a pandemic, it's difficult to meet with people to share updated information with them. Our hospitals are full, and everyone is kind of on their last straw of endurance. So it's all about trying to find a way to convince them to send their AF patients to me first and keeping those patients out of the ER, where Covid patients are receiving care. When patients come into the ER and say it's their first AF episode, the usual protocol is to get them back to primary care, so their thyroid-stimulating hormone (TSH) is checked, but very rarely are these folks experiencing hyperthyroidism. So why not send these patients to EP? I'll can check their TSH and also talk to them about their options for AF.

So I really think the biggest challenge with our referring physicians is making sure this information is out there. As with everything else, everyone is trying to keep up on new data, and there is so much new information about the pandemic as well. Do ER physicians and all of the surrounding ERs here know about STOP AF First? Probably not. I don't know about the newest treatment for non-Hodgkin's lymphoma — we just can't all keep up. It is a challenge, and it's our responsibility to get the information out there.

**How do you see this new clinical evidence influencing the ways in which EPs and referring physicians practice? How can we help EPs share information or new study data with referring cardiologists, especially now when there is a sea change in the way referring cardiologists have been approaching or thinking about AF for their patients?**

I'm hoping this evidence will encourage physicians to send their AF patients to me first, not last. We need to make sure that everyone sees this evidence, looks at the model, and realizes the PV potentials should be addressed early before the toxic effects of an antiarrhythmic take place, and before the patient has gone to the hospital. We're trying to keep everyone out of the hospital right now due to the pandemic, so it's important to avoid multiple cardioversions or multiple drugs that can induce pauses and side effects. Let's give patients good education, pulmonary vein isolation ablation with same-day discharge, and a continued conversation about risk factor modification.

It's going to take us EPs getting out there, doing grand rounds, and speaking to patients in person and using public forums to provide educational information for patients who were just diagnosed with AF. While the internet can be a great resource for information, it can also be misleading. A lot of times a patient will tell me, "My daughter was online and saw this," so we want to make sure that accurate information is out there to patients. ■

**We need to make sure that everyone sees this evidence, looks at the model, and realizes the PV potentials should be addressed early before the toxic effects of an antiarrhythmic take place, and before the patient has gone to the hospital.**

*This article is published with support from Medtronic.*

*Disclosure: Dr. Sorrentino reports participation as a speaker for two previous Medtronic programs.*