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EXPERT COMMENTARY

Highlights from Heart Rhythm 2016

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Heart Rhythm 2016 in San Francisco, CA was an incredible success by all measures. As other big cardiology meetings are decreasing, Heart Rhythm remains as strong as ever with more than 12,000 in attendance this year.

In this article, I share my five biggest takeaways from Heart Rhythm 2016.

1. The subcutaneous ICD works

Since the subcutaneous implantable cardioverter-defibrillator (S-ICD) was FDA approved in 2012, how has it fared in the real world? Fortunately, we now have the data from the Effortless Trial.¹

In this late breaking clinical trial, 985 patients from 45 European centers were studied. And the data look impressive. In fact, with an average follow up of 3.1 years, only 12% of patients suffered an inappropriate shock and only 2% of the S-ICD devices were extracted. These numbers compare very favorably to the traditional ICD. Of the extracted devices, the primary reason was a need for pacing or shocks that failed to terminate ventricular arrhythmias.

With regards to efficacy, the S-ICD performed every bit as well as the traditional ICD. Fully 89% of clinical ventricular tachycardia (VT)/ventricular fibrillation (VF) episodes were terminated with the first shock. Allowing for multiple shocks, 97% of VT/VF episodes were stopped.

The S-ICD is definitely here to stay. Fortunately, generator size and battery longevity have improved since the initial release. For patients who don't require pacing, and want to avoid potential lead complications, the S-ICD is an excellent option.

2. Leadless pacemakers are the future

Patients and doctors want a leadless pacemaker. While this technology is still in its infancy, it won't be long until the leadless systems can do everything the traditional pacemaker can do. Having just seen a patient with severe tricuspid regurgitation one year after pacemaker implantation, the sooner we can get this technology the better. In another late breaking clinical trial, Dr. Vivek Reddy presented a study² comparing acute and mid-term complications of leadless versus traditional pacemakers. In this study of 718 leadless VVI pacemakers (Nanostim, St. Jude Medical, St. Paul, MN) and 10,521 traditional pacemakers, the leadless system had far fewer complications.

Despite the high risk of device dislodgement (1%) and tamponade (1.5%), the leadless pacemaker had fewer complications both at the time of implantation and through the follow-up period. I should point out that this study included new implanters. I'm confident that with operator experience and better technology, these complications will only go down over time.

Fortunately, the Medtronic version of the VVI wireless pacemaker is now FDA approved. Hopefully, it won't be long until we have dual chamber or left ventricular options also available with these wireless pacemakers.

3. Evolving role of VT ablation

It seems as if every year at Heart Rhythm there is another big study comparing ablation to drugs for VT. This year was no exception.

The late-breaking clinical trial, the VANISH Study,³ was a 22-center trial involving 259 patients. The entry criteria were similar to the kind of patients you may see while on call at your hospital.

All patients had an ICD and all were on an antiarrhythmic. Despite an ICD and drug, these patients presented with ongoing VT. With this trial they were then randomized to VT ablation or two antiarrhythmics.

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With up to 4 years of follow-up, the VT ablation patients were 28% less likely to experience the composite primary end point of death, VT storm, or appropriate shocks. This ablation benefit was immediate and persisted until the end of the study.

Of course, these patients were certainly at risk for developing new VT circuits after their ablation. However, this study is reassuring in that this did not appear to happen.

4. Does warfarin cause dementia?

From a media perspective, this was the single biggest story from Heart Rhythm 2016. Based on the extensive worldwide coverage, I suspect you had a few worried patients call your office the next day. Let me share with you the real message of this study.

My partner, Dr. T. Jared Bunch, directed this study.⁴ This study evaluated 10,537 patients followed in the warfarin clinic at our hospital. Of these 10,537 warfarin-treated patients, 42% were being treated for atrial fibrillation and the other 58% for mechanical valves, deep venous thrombosis, pulmonary embolus, etc.

The main finding of this study was that the time in warfarin therapeutic range predicted the long-term dementia risk. In other words, regardless of the warfarin indication, patients with a poorly controlled international normalized ratio (INR) were at increased risk of dementia. Quite sobering was that the atrial fibrillation (AF) patients with a poorly controlled INR were observed to have the very highest dementia risk.

The take home message of this study is that if the INR can't be controlled, a newer anticoagulant is preferred unless the patient is on warfarin for a mechanical valve. Interestingly, other studies from our center have shown that the dementia risk appears to be much lower with a new oral anticoagulant (NOAC).

I suspect that the reason why NOACs carry a far lower dementia risk is because the anticoagulation is much more tightly controlled. Thus, these patients are less likely to have subclinical "microclots" from a subtherapeutic INR or "microbleeds" from a supratherapeutic INR.

5. The ongoing persistent AF dilemma

While pulmonary vein isolation (PVI) remains very effective in treating paroxysmal AF, the same cannot be said for persistent AF. Indeed, studies show that only 50% of persistent AF patients can be helped with PVI.

The STAR-AF Trial⁵ taught us that left atrial ablation lines and complex fractionated electrogram-guided ablations don't work. The "Holy Grail" of AF ablation has long been a mapping technology that allows us to see the source of AF.

We thought we were there at Heart Rhythm 2011 when Dr. Sanjiv Narayan first presented his FIRM (focal impulse rotor modulation) data as part of the CONFIRM

Trial.⁶ However, 5 years later, we may be no closer to the Holy Grail.

At a late-breaking clinical trial session, Dr. Andrea Natale presented the OASIS Study. This was the first randomized multicenter trial evaluating the rotor mapping technology from Topera/Abbot. This study was also simultaneously published in JACC.⁷

In the OASIS study, 113 persistent AF patients from three centers were randomized to FIRM-guided ablation alone, PVI plus FIRM, or PVI plus AF trigger ablation. The results were dismal.

The FIRM-only patients had a success rate of approximately 20% at 1 year. Adding PVI to FIRM didn't move the needle either as the success rate only jumped to about 50%, about what you would expect from PVI alone in persistent AF patients.

Is rotor/driver mapping dead?

Absolutely not. Having been involved in a number of studies myself, there definitely is at least a group of patients who have "mapable" rotors/driver that can be successfully targeted for ablation. The take home message is that either FIRM doesn't work or there still is not an easy way to interpret the FIRM maps. Either way, we need a better solution.

In the search for a persistent AF solution, there were two other late-breaking clinical trials that also came to humbling results. These were both surgical studies of persistent AF patients. The first looked at the role of ganglionic plexi (GP) ablation⁸ and the second with left atrial appendage excision.⁹

We have long known that the autonomic nervous system plays an important role in the initiation and maintenance of AF. There have also been countless studies showing that targeting these neural inputs helps with AF. However, in the largest randomized trial to date, there was no benefit. In a surgical study of 240 patients randomized to PVI plus GP ablation versus PVI alone, researchers found that targeting the GPs offered no clinical benefit. If anything, there was only harm.

Even though these surgeons completely eliminated all vagal responses, they still couldn't improve the success rate. What this study did show is that targeting GPs resulted in more pacemakers and more perioperative bleeding.

Equally sobering was a Russian late-breaking clinical trial looking at the effect of excising the left atrial appendage (LAA) for the treatment of AF. While surgeons have been cutting off the LAA for years, we really have had no solid data on what this does to the AF. In this study of 176 patients randomized to PVI plus LAA excision versus PVI alone, excising the LAA had no beneficial effect on freedom from AF. This came as a complete surprise to me given the previous work of Andrea Natale.¹⁰

Despite this negative study, there has to be at least a subset of patients who would benefit from eliminating the LAA. I should note that a recent study has shown that electrically isolating the LAA puts the patient at an extremely high risk of stroke.¹¹ This stroke risk remains

high even if the patient is on anticoagulation. Thus, based on this most recent study, if the LAA is ever targeted for AF ablation, the appendage should also be occluded or excised.

Perhaps the real reason why nothing seems to work very well for persistent AF is because persistent AF is really a lifestyle disease. It just may be that if we really want to make a dent in persistent AF, we should focus more of our efforts on lifestyle modification.

So there you have it, my top five highlights from Heart Rhythm 2016. What were your big takeaways? Please drop me a line and let me know.

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