LETTER FROM THE EDITOR IN CHIEF

Dear Readers,

It is hard to believe that 2013 is now gone and we are now in 2014! So much has happened in our field during 2013. As I reflect back on the year it has been, like last year, I would like to discuss the 10 biggest stories in our field for 2013.

10. VT Ablation Reduces Mortality

There is now a growing body of data that suggests VT ablation for the ICD patient with recurrent shocks improves survival. The latest study was just published on December 10, 2013 in Heart Rhythm\(^1\). In this study, my colleague, Dr. Jared Bunch looked at 102 consecutive patients at Intermountain Healthcare with structural heart disease who underwent VT ablation for recurrent ICD shocks and compared these patients to 2088 patients with an ICD and no history of an appropriate shock and 817 patients with an ICD and a history of an appropriate shock.

Interestingly, the patients who underwent VT ablation had a survival similar to those patients with an ICD who never received a shock. In comparison to the group of patients with ICD shocks who did not undergo ablation, mortality was reduced by 43% with catheter ablation of VT.

While these are not data from a randomized clinical trial, they do represent the experience from multiple centers within one large healthcare system. Until future studies conclusively answer this question, these data are very reassuring that VT ablation in patients with recurrent ICD shocks can potentially be life saving.

9. Athletes and ICDs

The teaching has always been that athletes with ICDs should not participate in competitive sports. Dr. Rachel Lambert and colleagues have now challenged this dogma with their article published in Circulation this past year\(^2\). In this study of 372 competitive athletes or athletes participating in high risk sports, they found that most athletes with ICDs can safely engage in vigorous and competitive sports without fear of death or their ICD not functioning appropriately during competition.

In this study, running, basketball, and soccer were the most common sports. All episodes of VT or VF, even during athletics, were ultimately terminated by the ICD. Moreover, despite competitive athletics, they found that freedom from lead malfunction was 97% at 5 years and 90% at 10 years.

This study is important in that an ICD is not the end of an athlete’s career. Rather, the opposite is now true; an ICD will allow athletes to continue to compete at a high level.

8. The Sub-Cutaneous ICD

For nearly a decade we have followed the development of the sub-cutaneous ICD. Now in 2013, it finally arrived with FDA approval in the U.S. Importantly, in the August 27, 2013 issue of Circulation\(^3\), Dr. Weiss and colleagues showed for the first time that this therapy is just as safe and effective as the traditional transvenous ICD.

In this prospective, nonrandomized, multicenter trial of 330 patients followed for 11 months, all 38 spontaneously occurring episodes of VT/VF were successfully terminated. Moreover, the 180-day system complication-free rate was 99%. These numbers are impressive for a new technology that represents a paradigm shift in ICD therapy.
At our center we have been eagerly awaiting this new technology. Unfortunately, due to production problems with Boston Scientific, we have yet to have this technology in our hands. Hopefully, as Boston Scientific can correct the production problems, centers that were not part of the initial studies can also have access to this new technology.

7. Watchman is Superior to Warfarin

At the Annual Scientific Sessions of the Heart Rhythm Society this past year in Denver, Dr. Vivek Reddy presented this late-breaking clinical trial. In this study he showed that after 2,621 patient years of follow-up, left atrial appendage occlusion with Watchman was superior to systemic warfarin therapy for AF patients with regards to the composite primary end-point that included stroke, systemic embolism, or cardiovascular death.

This study is important as previous data only showed that Watchman was “non-inferior” to warfarin. While our European colleagues have been able to provide their patients with this therapy for years, it is expected that the data now coming out from the PROTECT-AF and PREVAIL Trials is now “good enough” for the FDA to finally approve this life-saving therapy in the U.S.

While this therapy is expected to be finally approved in 2014 for U.S. patients, the next step will be to make sure that physicians are adequately trained with this device as it rolls out so that the 5% risk of pericardial effusion seen in the PROTECT-AF Trial is not repeated with market release of this product (the pericardial effusion risk dropped to approximately 2% in subsequent studies). Stay tuned, as this will be an exciting year with the release of Watchman!

6. Pacemaker or ICD Implantation without Stopping Warfarin

Should warfarin be stopped with device implantation has been a recurring question for the last number of years. Finally, this question was put to rest. Dr. David H. Birnie presented the results from the BRUISE CONTROL Trial as a late-breaking clinical trial at HRS this past year. These results were also simultaneously published in the New England Journal of Medicine.

In this multicenter randomized controlled trial of 681 patients at high risk for stroke randomized to pacemaker/ICD implantation with uninterrupted warfarin (mean INR 2.3) versus heparin bridging, they found that the risk of a pocket hematoma was approximately four times lower with uninterrupted warfarin. There was no statistical difference in thromboembolic complications between the two groups as the number of events was low. However, given the marked reduction in pocket hematomas with uninterrupted warfarin, the data safety monitoring board recommended early termination of this study.

Not surprisingly, with the four-fold reduction in pocket hematomas with uninterrupted warfarin, one would naturally ask what kind of a bridging protocol was used in this study. In this study, they used low-molecular weight heparin until 24 hours prior to the surgery or unfractionated intravenous heparin until four hours prior to the surgery. Following implantation, unfractionated intravenous heparin was started 24 hours after surgery and continued until the INR was therapeutic.

The findings from this study will undoubtedly make it into the guidelines. The next question would be is what should be done in these high-risk stroke patients for routine dental, gastrointestinal, or other common medical procedures?

5. Biventricular Pacing for Complete Heart Block and EF of 50% or Lower

As patients with an impaired ejection fraction who require continuous pacing do not fare well with right ventricular pacing alone, we have long speculated that even milder forms of heart failure would probably do better with cardiac resynchronization (CRT) therapy. Finally, this study was done.

This title of this study is the BLOCK-HF Trial and Dr. Anne Curtis and colleagues published it in the New England Journal of Medicine this past year. Based on the results of this study, we finally know how best to manage these patients with complete heart block and mild heart failure. In this study, 691 patients with complete heart block and an EF of 50% or lower were randomized to CRT or RV only pacing. The mean EF in this study was approximately 43%.
Of the patients randomized to CRT, they enjoyed a 26% reduction in the primary end-point of death, heart failure visit requiring intravenous therapy, or a 15% increase in the left ventricular chamber size. The take home message of this study is that in patients with complete heart block who will require 100% pacing, if the EF is in any way impaired then biventricular pacing is the desired pacing mode.

4. Starting Warfarin Increases the Risk of Stroke

In comparison to recent years, there were not as many new developments in the world of anticoagulation therapy. However, there was a very provocative study that made my top 10 list for 2013. This study was published December 18th in the European Heart Journal. In this study of over 70,000 patients, they found that in the first 30 days of initiating warfarin therapy that the risk of a stroke was 71% higher in warfarin treated patients. These data suggest that there is a transient hypercoagulable state that exists for about the first month when initiating warfarin.

This study is highly provocative as it challenges our current treatment paradigm. Perhaps we should not start and stop warfarin for medical procedures. Moreover, should we be using the novel anticoagulants, particularly when starting anticoagulation for the first time following a procedure like a transesophageal echo guided cardioversion? Certainly, more studies are required to see if warfarin really does result in a transient hypercoagulable state when first starting this drug.

3. Humbling Results from Real World AF Ablation Procedures

While the number AF ablation procedures have exploded world-wide, there remains a dark side that is rarely discussed, namely that of complications. For those of us who work in this space, we are acutely aware of the myriad of problems that could occur from one of these procedures.

Experience really is something that can determine whether or not a patient will live following the procedure. This reality was hammered home in a recent study that was published online in Circulation on September 23, 2013. In this study of 93,801 AF ablations performed from 2000 to 2010 in the U.S., they found that 1 in every 200 patients undergoing AF ablation died before leaving the hospital.

This is a startling statistic that I am still trying to wrap my head around. For every 200 patients undergoing AF ablation in the U.S., one will ultimately die before leaving the hospital. When we have looked at our outcomes very closely, we cannot even begin to fathom how so many patients could die from an AF ablation procedure.

When the authors in this study drilled down as to why all of these deaths occurred from AF ablation, they found that operators who perform less than 25 AF ablation procedures each year and centers that perform less than 50 AF ablations annually pose the greatest risk to patients. Clearly, we need to do a better job at educating ourselves and ensuring both our institutions and we, as operators, have adequate training and volumes if we are going to perform these high-risk procedures.

2. Nanostim Wireless Pacemaker System

The Nanostim Wireless Pacemaker System is another technology that has been long awaited. As we all know, the Achilles Heel of pacemaker/ICD therapy has always been the leads. Now finally, we can get away from the wires.

In another late-breaking clinical trial session at Heart Rhythm 2013, Dr. Vivek Reddy presented the results of the first 33 VVI Nanostim pacemaker implantations from the First-in-man Leadless Study. While the patients included in this study were limited, the procedure appears safe thus far. Based on the results of this study, this device is now approved for use in Europe and we await further trials in the U.S. before FDA approval.

This and other similar technologies currently in development, will radically change the way manage device patients. No longer will we have to worry about the wound infections in the pectoral area or wire fractures. Everything we need to pace the heart will all be located locally within the heart.
1. Reversing Atrial Fibrillation

Dr. Prash Sanders and colleagues should be commended for the biggest story of 2013, namely that atrial fibrillation is a potentially reversible disease. For too long, we, as an EP field, have focused on the latest and greatest treatment options for this disease rather than take a step back and see what is the cause of this AF epidemic and what can be done to reverse the process.

In this study, which was presented at the AHA this fall and simultaneously published in JAMA\textsuperscript{8}, 150 overweight and obese AF patients were randomized to weight loss or lifestyle counseling. Interestingly, after a median follow-up of 15 months, the weight loss group lost a total of 32 pounds (14.3 kg). Amazingly, the weight loss group showed 2.5 times less AF as well as a reduction in interventricular septal thickness and left atrial area.

This study really is a wakeup call for all physicians who manage AF. For overweight and obese patients with AF, rather than reach for our prescription pad to write for potentially toxic antiarrhythmics or recommend an ablation procedure, we should work first on weight loss with these patients.

I hope that you have enjoyed my top 10 list for 2013 and that this Journal continues to be a valuable source in keeping you up to date on the latest innovations in the field of cardiac rhythm management.

Warm regards,

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