Late-Breaking Abstract Session

Ballroom West

Thursday, May 10, 2012

10:30 a.m. - 12:00 p.m.
SAFETY OF SPORTS FOR PATIENTS WITH ICDs: RESULTS OF A PROSPECTIVE MULTINATIONAL REGISTRY

Rachel Lampert, MD, FHRS, Brian Olshansky, MD, FHRS, Hein Heidbuchel, Christine Lawless, Elizabeth Saarel, Michael Ackerman, Hugh Calkins, Mark Estes, Mark Link, Barry Maron, Frank Marcus, Melvin Scheinman, Bruce Wilkoff, Douglas Zipes, Charles Berul, Alan Cheng, Ian Law, Michelle Loomis, Cheryl Barth, BS, Cynthia Brandt, James Dziura, Fangyong Li and David Cannom. Yale University School of Medicine, New Haven, CT, University of Iowa, Iowa City, IA, University Hospitals Leuven, Leuven, Belgium, Sports Cardiology Consultants LLC, Chicago, IL, University of Utah, Salt Lake City, UT, Mayo Clinic, Rochester, MN, Johns Hopkins, Baltimore, MD, New England Medical Center, Boston, MA, Minneapolis Heart Institute, Minneapolis, MN, University of Arizona, Tucson, AZ, University of California, San Francisco, San Francisco, CA, Cleveland Clinic Foundation, Cleveland, OH, Indiana University, Indianapolis, IN, Children's National Medical Center, Washington, DC, Michigan Heart, Ypsilanti, MI, Los Angeles Cardiology Associates, Los Angeles, CA

Introduction: International consensus statements recommend against participation in competitive sports for patients with ICDs, yet the risks are unknown. We undertook a prospective multinational registry to determine the incidence of serious adverse events in ICD patients participating in sports. The primary endpoint of the study was death or resuscitated arrest during sports, or injury during sports due to arrhythmic symptoms and/or shock. Secondary endpoints included system malfunction and incidence of ventricular arrhythmias (VA) requiring multiple shocks for termination.

Methods: Athletes with ICDs (N=372; age 10-60 years) participating in competitive (N=328) or dangerous (N=44) sports were recruited by sites (N=211 subjects) or through internet patient advocacy groups (N=161). Sports-related and clinical data were obtained by phone interview and medical records. Follow-up phone calls occurred every 6 months. ICD shock data and clinical details of lead malfunction were adjudicated by two electrophysiologists.

Results: Median age was 33 years (89 subjects < 20 years), 33% female. Mean EF was 60%; 42% had a pre-ICD history of VA. The most common diagnoses were LQTS, (N=73), HCM (N=65), and ARVC (N=53). Running, basketball, and soccer were the most common sports. Overall 138 patients were participating at interscholastic (N=67) or state/national levels (N=71). Over a median follow-up of 31 months, (iqr 21-46), 18% of athletes received shocks (table). There were no occurrences of either primary endpoint: 1) death or resuscitated arrest, or 2) arrhythmia- or shock-related injury, during sports. Freedom from lead malfunction was 97% at 5 years (from implant) and 90% at 10 years. There were 8 VA episodes for which multiple shocks were received: 1 at rest, 4 competition/practice-related, 3 with other physical activity, although all were ultimately terminated by the device. These occurred in 7 people: 3 CAD, 1 CPVT, 2 idiopathic VF, 1 HCM.

Conclusions: While 9% of athletes received a shock during competition/practice, there were no serious adverse sequelae. Lead malfunction rates were similar to that reported previously for ICD patients. These data do not support competitive sports restriction for all athletes with ICDs.

| Shock events. Values refer to total events/unique individuals. %s refer to % of study population |
|--------------------------------------------------|-------------------|-------------|---------|-------|
| Rhythm               | competition/practice | other physical activity | Rest | total |
| VT                   | 20/15              | 13/10        | 11/8      | 44/33 (9%) |
| VF                   | 8/6               | 2/2          | 10/5      | 20/13 (4%) |
| Sinus Tach           | 7/6               | 6/3          | 1/1       | 14/10 (3%) |
| Atrial Fib           | 5/3               | 10/6         | 2/2       | 17/11 (3%) |
| Other SVT            | 2/2               | 1/1          | 0/0       | 3/3 (1%)  |
| Noise                | 0/0               | 0/0          | 1/1       | 1/1      |
| T-wave oversensing   | 2/2               | 1/1          | 1/1       | 4/4 (1%)  |
| Total                | 44/34 (9%)        | 33/23 (6%)   | 26/18 (5%)| 103/67 (18%) |
INDEPENDENT MULTICENTER STUDY OF RIATA AND RIATA ST ICD LEADS

Raed Abdelhadi, MD, Samir Saba, MD, FHRS, John DiMarco, MD, FHRS, Melanie Gura, RN, FHRS, Daniel Kramer, Christopher Ellis, MD, Raveen Bazaz, MD, FHRS, Pamela Mason, MD, Michael Coronado, MD, David Hayes, MD, FHRS, Paul Friedman, MD, FHRS and Robert Hauser, MD, FHRS. Minneapolis Heart Institute, Minneapolis, MN, University of Pittsburgh Medical Center, Pittsburgh, PA, University of Virginia Health System, Charlottesville, VA, Summa Health System, Akron, OH, Beth Israel Deaconess Medical Center, Boston, MA, Vanderbilt Heart and Vascular Institute, Nashville, TN, Mayo Clinic, Rochester, MN

Introduction: Riata and Riata ST ICD leads were recalled due to insulation defects. No independent multicenter study has evaluated these leads. Thus, we assessed the long-term survival of Riata (RIA) and Riata ST (RST) leads and compared them to Quattro Secure (QS) ICD leads.

Methods/Results: Data were collected retrospectively from 7 centers. K-M survivals (SURV) were calculated for all cause failure, including leads with normally functioning externalized conductors (EXC), and for leads that were electrically malfunctioning. SURVs were compared with the log rank test. Average follow-up (yrs) were: RIA-4.3±2.5; RST-3.5±2.0; QS-3.2±2.1 (p<0.0001 for RIA vs. RST). All cause SURVs for 774 RIA, 307 RST, and 1668 QS leads are shown on the top and the malfunction SURVs are below. Compared to QS, Riata all cause and malfunction SURVs were significantly worse (p<0.0001 and 0.0003). RST SURVs were not different than QS (p=0.626 and p=0.997). RIA SURVs were worse than RST (p=0.0106 and 0.0176). Overall 43 RIA, 4 RST, and 23 QS leads malfunctioned; 8 of 28 (29%) EXC leads malfunctioned. Failure rates (failures/year/%) were: RIA-1.9; RST-0.47; QS-0.43. No clinical variable (age, gender, ICD indication, cardiac disease, EF) predicted RIA or RST failure.

Application: In this large multicenter study, the SURVs of Riata but not Riata ST leads were significantly worse than Quattro leads. However, Riata ST follow-up was shorter than Riata. No clinical variable examined was associated with failure. Nearly a third of leads with externalized conductors were malfunctioning.

Next Steps/Future: Studies are needed to determine how to best monitor RIA and RST leads, and how to manage them safely.

VOLUME OF DENERVATED MYOCARDIUM IS A NOVEL PREDICTOR OF VT/VF: PREDICTION OF ARRHYTHMIC EVENTS WITH POSITRON EMISSION TOMOGRAPHY (PAREPET) STUDY

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Background: The frequency of sudden cardiac arrest (SCA) is inversely related to LV function yet many events occur in patients with an EF > 35% who are not currently candidates for ICD therapy. We hypothesized that quantifying regional inhomogeneity in myocardial sympathetic innervation and/or viability (scar and hibernating myocardium) could provide an approach to identify subgroups at highest risk of SCA.

Methods: To initially test this, we prospectively enrolled CAD
patients (n = 204) who were candidates for ICD placement for the primary prevention of SCA in the PAREPET study (NCT01400334). Average age was 67 ± 11 years with NYHA functional class 2.1 ± 0.8 CHF and an EF of 27 ± 9%. Cause specific mortality from SCA was defined using modified Hinkle-Thayer criteria or ICD discharge for VF (or VT > 240 bpm). After baseline echocardiography and clinical evaluation, substrate remodeling was quantified using PET to image perfusion (¹⁵N-ammonia; NH₃), the extent of sympathetic denervation (¹³C-meta-hydroxyephedrine; HED) and infarction (insulin-stimulated¹⁸F-2-deoxyglucose; FDG).

Results: Median follow-up was 4.2 years and cardiac mortality was 34%, of which half was from SCA (16%). The figure summarizes SCA event-free survival imaging each substrate (in tertiles). As continuous variables, the volume (% LV) of denervated myocardium was a strong determinant of SCA (p = 0.001). By multivariate analysis (including EF and BNP), denervated myocardium (>37.6% LV) remained an independent predictor of SCA (10.3%/year vs. 3.0%/year; HR = 3.5, p = 0.009) whereas EF, infarct volume and hibernating myocardium were not. Additional predictors by multivariate analysis included LV end-diastolic volume index, creatinine, and no ACE/ARB therapy.

Conclusions: These data indicate that patients with ischemic cardiomyopathy at highest risk of SCA can be identified by evaluating inhomogeneity in myocardial sympathetic innervation. Since this is independent of scar volume and EF, quantifying the extent of sympathetic denervation could afford a new approach to selecting patients with relatively preserved systolic function who are at risk of arrhythmic death.

Sudden Cardiac Arrest Event-free Survival

Denervated  Hibernating  Infarcted

Tertile  Lowest  Intermediate  Highest

Survival (%)

Follow-Up (Years)

p = 0.001

p = 0.05

p = 0.05

11:30 a.m.

LONG TERM FOLLOW-UP IN THE SUDDEN CARDIAC DEATH HEART FAILURE TRIAL (SCD-HEFT)

Gust Bardy, MD, Kerry Lee, PhD, Daniel Mark, MD, MPH, Jeanne Poole, MD, Daniel Fishbein, MD, Robin Boineau, MD, Anne Hellkamp, MS, Linda Davidson-Ray, MS, Kevin Anstrom, PhD, George Johnson, Jill Anderson, BSN and Per Reinhard, MD. Seattle Institute for Cardiac Research, Bellevue, WA, Duke University, Durham, NC, University of Washington, Seattle, WA, National Institutes of Health, Bethesda, MD

Background: SCD-HeFT began in 1997 and remains the only placebo-controlled ICD trial, testing amiodarone vs. placebo and single lead shock only ICD therapy vs. placebo for the prevention of death in CHF. A total of 2521 pts were randomized on a 1:1:1 basis in the 3 arms. Initial follow-up ended October 31, 2003. Amiodarone was shown to be unhelpful and ICD therapy provided a 23% survival advantage over a median 45.5 month follow-up period. When initial follow-up ended, 1855 pts were alive. Despite the outcome of SCD-HeFT, questions remain regarding the long-term role of ICD therapy in patients with heart failure primarily because of the numbers needed to treat to save a life and ICD complications. The purpose of this project was to perform a one-time follow-up of the long-term survival of the SCD-HeFT cohort during the years 2010 to 2011.

Methods: We sought mortality data on the 1855 surviving SCD-HeFT pts since October 31, 2003 to compare outcome in the 3 arms of the trial (ICD, placebo and amiodarone) based on an intent-to-treat (as randomized) analysis and an on-treatment analysis. The 666 deaths from the original study were integrated into the long-term mortality data to generate 10+ year survival curves. Outcome data were also compared in the original major subgroups: ischemic vs. non-ischemic and NYHA Class II vs. Class III heart failure. Where sufficient data were available, long-term ICD use rates, complication rates, lead failure rates and replacement rates were measured as well as NYHA Class.

Results: Mortality data were available on 2291 (91%) of the original 2521 patients enrolled in SCD-HeFT for a median follow-up period of 11.0 years. The median age of survivors, regardless of therapy, was 67 yrs with 29% of those alive being female and 22% being minorities. The median EF of the entire population at last known measurement was 27.5%. Last known NYHA functional status was Class I in 320 (13%), Class II in 1166 (46%), Class III in 836 (33%) and Class IV in 199 (8%). Cardiac transplantation was known to have occurred in 99 (4%) of the population. For the 786 pts in whom we had long-term ICD and amiodarone use data, from the time of the end of the original trial to long-term follow-up, 555 (64%) had received some type of ICD, and 231 (30%) had received amiodarone. The overall 10-year (Kaplan-Meier) mortality rate was 54% (56% for men and 48% for women). The original ischemic and non-ischemic subgroups, at the time of randomization, had 64% and 43% 10-year mortality rates, respectively. The original NYHA Class II and Class III subgroups had 47% and 70% 10-year mortality rates, respectively.

Conclusions: Follow-up in SCD-HeFT patients after a median of 11.0 years provides critical insights into the long-term outcome of patients with moderate CHF. Differences in outcome depending upon therapy will be revealed at the time of presentation.
SAFETY AND EFFICACY OF A SUBCUTANEOUS IMPLANTABLE-DEFIBRILLATOR

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Introduction: A subcutaneous implantable defibrillator (S-ICD) that does not require a transvenous lead has been developed. The purpose of this study was to evaluate the safety and efficacy of the S-ICD for the treatment of life-threatening ventricular arrhythmias.

Methods: The S-ICD System IDE Clinical Investigation is a prospective, non-randomized, multicenter clinical study. The study included patients with any standard indication for ICD who did not require pacing. The efficacy endpoint was the induced ventricular fibrillation (VF) conversion rate, defined as 2 consecutive successful conversions out of a possible 4 attempts in the same shock polarity. The appropriate detection and conversion of spontaneous episodes were also evaluated. The safety endpoint was the 180-day S-ICD System complication-free rate.

Results: Device implantation was attempted in 321/330 pts enrolled. The cohort was 74% male with a mean age of 52 years and mean ejection fraction of 36%. The ICD indication was primary prevention in 80%, and 41% had a prior myocardial infarction while 11% had a channelopathy. A previous transvenous ICD had been implanted in 13%. No fluoroscopy was used in 95% of cases. Acute VF conversion testing was successful in 100% of the 304 patients (95%) who completed the testing protocol. The rate of major complications related to device implantation was 4.4% at 30 days, and 7.9% at 180 days. A total of 23 pts (7.2%) required 26 repeat surgeries for suboptimal position (n=5), electrode movement (n=3), incomplete electrode connection (n=1), device movement (n=1), discomfort or incision problem (n=9), premature battery depletion (n=2), communication failure (n=2), or oversensing (n=3); and 4 additional pts underwent device removal for infection. During follow up, 68 episodes of VT/VF were successfully treated, and 39 pts received an inappropriate shock. There were 8 deaths; 1 of the 2 sudden deaths was associated with an appropriate shock; the device was unavailable to interrogate for the other.

Conclusions: The totally subcutaneous defibrillator (S-ICD) is safe and effective for the treatment of life threatening ventricular arrhythmias.