

for group 2 ( $p < 0.0001$ ), and was  $-30.1 \pm 14.6\%$  for group 2a and  $-21.3 \pm 10.9\%$  for group 2b ( $p < 0.0001$ ). The Delta-RR2 was  $+3.6 \pm 12.6\%$  for group 1 and  $-4.0 \pm 14.6\%$  for group 2 ( $p < 0.001$ ), and was  $-5.8 \pm 12.3\%$  for group 2a and  $+0.3 \pm 17.6\%$  for group 2b ( $p = 0.001$ ).  
**CONCLUSION:** Majority of VT/VF episodes occurred in forms of storms. Episodes during storms were associated with greater changes in R-R intervals compared to discrete episodes. This raises the possibility of using changes in R-R intervals as an indicator to determine patients' propensity to experience VT/VF storms.

#### 1067-108 Is One Successful VF Conversion Adequate for Safe ICD Implantation?

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**Background:** Multiple successful conversions of ventricular fibrillation (VF) have been recommended as the minimum criteria for safe defibrillator (ICD) implantation, because of the statistical probability of success curve for defibrillation. We postulated that a single success at a low energy (14 J) would provide an adequate safety margin for devices programmed to maximum energy (31 J).

**Methods:** The Low Energy Safety Study (LESS) enrolled 720 patients at 32 centers undergoing initial ICD implantation with a dual coil transvenous lead and active pulse generator (triad configuration). At implant the defibrillation threshold (DFT) was determined using a rigorous protocol beginning at 14 J that required at least 4 shocks to determine the DFT $\pm$ . Half of all patients were then randomized to chronic programming with all shocks at maximum energy and the conversion rates for spontaneous VF (ventricular arrhythmias with rates  $> 200$  bpm) were evaluated.

**Results:** In LESS, 318 patients were randomized to all shocks at 31 J, including 254 with success on their initial attempt at 14 J. During a mean follow-up duration of  $24 \pm 12$  months, the full cohort experienced 112 spontaneous episodes of VF, of which 103 (92%) were successfully converted with the first shock and 109 (97.3%) were successfully converted with the first 2 shocks. In the subset with the 14 J initial attempt success, 66 spontaneous VF episodes occurred, of which 59 (89.4%) were successfully converted with the first shock and 64 (97%) were successfully converted with the first 2 shocks. The device eventually converted all episodes in both groups.

**Conclusions:** An implant criterion of one success at 14J appears adequate and deserves further study.

#### 1067-109 Clinical Features and Causes of Coaxial Polyurethane ICD Lead Failure

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**Background:** The failure of an ICD lead may prevent the detection or termination of VT/VF, or the treatment of a bradyarrhythmia. Coaxial polyurethane ICD leads (ICD-L), Transvene RV models 6936/6966 (Medtronic, Inc.) were introduced in 1991. According to the manufacturer, 24, 625 U.S. implants have been registered, and an estimated 14,400 remain active. Recent reports suggest that these ICD-L may be prone to failure.

**Methods:** We searched the Multicenter Registry and FDA's MAUDE (Manufacturer and User Facility Device Experience) databases for ICD-L device failures. Lead complications due to infection, displacement, and iatrogenic causes were excluded. As of September 2001, the Registry had received 22 reports from 8 North American centers, and MAUDE contained 438 reports, including 79% from the manufacturer and 21% from user facilities.

**Results:** The mean time to failure for these 460 leads was  $3.3 \pm 2.0$  years (range:  $< 1$  month-8 years). The primary signs of failure were available for 299 events: inappropriate shocks or antitachycardia therapy-39% (118/299), oversensing-15% (46/299), undersensing-7% (20/299), failure to defibrillate-3% (8/299), non-capture or high threshold-15% (45/299), impedance change-15% (46/299), and other-5% (16/299). Major clinical events included 10 deaths and 17 life-threatening emergencies. Specific causes of failure were reported for 267 ICD-L: conductor fracture-68% (181/267), disrupted insulation-31% (84/267), and fixation mechanism-1% (2/267); clavicular crush was noted in 6% (16/267). Analyses of 110 ICD-L that were removed and returned to the manufacturer revealed that fracture often involved the high voltage coil (37/72) or multiple conductors (17/72) and the 80A polyurethane middle (18/38) or outer (17/38) insulation. **Conclusion:** ICD-L appear to fail for reasons related to the coaxial design, 80A polyurethane insulation, and implant technique. Because of the potentially serious clinical consequences of ICD-L failure, studies are needed to determine the likelihood of failure, and to guide the safe management of patients who have these models.

#### 1067-110 Ventricular Arrhythmia Recurrence After Quiescent Periods in Patients With Implantable Cardioverter-Defibrillators

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**Background:** Current AHA/NASPE recommendations suggest a 6-month symptomatic arrhythmia event free interval following placement of an implantable cardioverter defibrillator (ICD) before resumption of driving. An additional 6-month observation period is advised if arrhythmia recurs. In this study, we postulated that the quiescent time to recurrence of arrhythmia may be useful to predict risk of future arrhythmia recurrences in ICD patients (pts).

**Methods:** Data from 254 consecutive ICD pts was reviewed. The interval after ICD implant to each ventricular tachycardia (VT)/ventricular fibrillation (VF) episode treated by ICD pacing or shock was identified. Pts (mean age  $64 \pm 14.1$  years) were followed at 3 to 6 month intervals for an average of  $24 \pm 14.6$  months. Mean left ventricle ejection fraction (LVEF) was  $35 \pm 14.5\%$ .

**Results:** Indication for ICD implant was spontaneous sustained VT (52%) or VF (35%), or inducible sustained VT (13%). One hundred forty (55%) pts experienced at least one ICD treated ventricular arrhythmia. A total of 1920 episodes were treated, VF accounting for 285 (15%). Amiodarone and  $\beta$  blockers, including sotalol were used in 30% and 58% of pts at discharge, and 32% and 58% at the end of follow up period, respectively. The recurrence rates for ICD treated VT/VF during a 6 month period following quiescence periods of 3, 6, 9 and 12 months immediately post implant were 24%, 21%, 19% and 17%, respectively. Conversely, a 6-month quiescent period starting after a treated arrhythmia was associated with 45% recurrence risk ( $p = 0.001$  vs risk with a 'no arrhythmia' 6 month period). Logistic regression identified that a low LVEF ( $< 30\%$ ) was the only significant predictor of arrhythmia recurrence ( $p = 0.02$ ).

**Conclusion:** Subsequent VT/VF recurrence risk in ICD pts decreases inversely with the length of arrhythmia free period. Further, for comparable followup periods, a quiescent period immediately after implant is associated with a lower recurrence risk than is a similar length quiescent period after a treated arrhythmia. However, even long quiescent periods are ultimately associated with worrisome VT/VF recurrence. This finding requires consideration when providing driving advice for ICD pts.

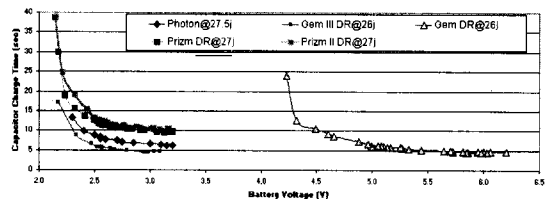
#### 1067-111 The Relation of Capacitor Charge Time and Output Energy to Battery Voltage Compared in Multiple Implantable Cardioverter Defibrillator Pulse Generators

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**Background:** Comparative data is lacking on implantable cardioverter-defibrillator (ICD) systems on the effect of battery voltage on capacitor charge time and output energy.

**Methods:** ICD pulse generators were attached to a rhythm simulator and allowed to pace and shock into fixed loads. Each ICD was programmed to deliver shocks at 4 energy levels with 5 episodes for each level (20 episodes/day). Battery voltage was measured at the beginning of every sequence and charge time was recorded immediately after each shock. The shock output was measured at each energy level by oscilloscope and delivered energies calculated. Delivered energy was then compared to programmed outputs as well as battery voltage. This was continued until battery depletion. The ICDs tested were: Gem DR, Gem III DR (Medtronic), Photon (St. Jude) and Prizm DR, Prizm II DR (Guidant).

**Results:** A family of graphs was generated showing the relationship of battery voltage to charge time at various energy levels (example). ICDs which program delivered energy had an error in measured energy as high as 10%, independent of battery voltage.



**Conclusions:** An inverse relationship of battery voltage to capacitor charge time was found with differences in charge time between devices remaining constant. Discrepancy between programmed delivered energy and measured energy was highest in devices with shorter charge times and programmable delivered energy. Measured shock output energies were stable throughout the life of all devices.

### POSTER SESSION

#### 1068 Noninvasive Risk Stratification

Sunday, March 17, 2002, 3:00 p.m.-5:00 p.m.

Georgia World Congress Center, Hall G

Presentation Hour: 4:00 p.m.-5:00 p.m.

#### 1068-112 Postural Response of Low Frequency Component of Heart Rate Variability Is an Increased Risk for Mortality in Patients With Coronary Artery Disease

Jun-ichiro Hayano, Seiji Mukai, Seiichiro Sakata, Hidekatsu Fukuta, Shinji Ishihara, Genjiro Kimura, *Third Department of Internal Medicine, Nagoya City University Medical School, Nagoya, Japan.*

**Background:** Analysis of heart rate variability (HRV) during head-up tilt testing (HUT) is widely used as a cardiac autonomic function test, but its prognostic value in coronary artery disease (CAD) is unknown. We examined if autonomic functions assessed by HRV during a standardized HUT predicts risk for death in patients with stable CAD.

**Methods:** In a cohort of 250 patients with CAD undergoing elective coronary angiography, we analyzed HRV during standardized HUT under paced breathing with discontinuing all medications. The patients were subsequently followed up for 99 months and the prognostic value of HRV was examined.

**Results:** During the followed-up, there were 25 deaths (10%); 13 from cardiac causes and 12 from non-cardiac causes. Cox regression analysis adjusted for cardiovascular risks revealed that increased postural change (upright minus supine) in low-frequency power (LF) predicted an increased risk for cardiac death (RR [95% CI] per 1-in[ms<sup>2</sup>] increment, 4.36 [1.64-11.6]), while neither high-frequency component nor its response to HUT predicted any form of death. When the patients were trichotomized by the level of postural LF change (large drop  $< 0.6$  ln[ms<sup>2</sup>], small drop and rise  $> 0$  ln[ms<sup>2</sup>]), the 3 groups did not differ in clinical features or CAD severity at baseline or coronary interventions dur-