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Presentation Title: ICD Therapy for Fast Ventricular Tachycardia or Ventricular Fibrillation is a Surrogate Endpoint for Mortality in MADIT II

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Abstract Body: Introduction: Effective primary prevention of sudden cardiac death with implantable defibrillators (ICD) is well demonstrated in patients with coronary disease and depressed left ventricular function. The MADIT II trial and other trials which have proven a mortality benefit of the ICD have used all cause mortality as the primary endpoint. Most episodes of fast ventricular tachycardia (VT) or ventricular fibrillation (VF) would be fatal without an ICD. The use of ICD therapy as an alternative clinical trial endpoint to demonstrate the efficacy of an ICD has been suggested, but remains controversial. Hypothesis: The difference in mortality between the conventional arm (CONV) and the ICD arm will be approximated by the event rate for fast VT or VF. Methods: The authors classified ICD therapy events (electrograms) for rate and type of arrhythmia treated. Kaplan-Meier survival curves were created for: 1) CONV total mortality, 2) ICD total mortality, and 3) composite endpoint of 1st therapy for VF or fast VT (>240 bpm) or total mortality (ICD group only). Results: 2-year mortality was 18% (88 of 490 pts) in CONV and 13.3% (96 of 720 pts) in ICD; fast VT/VF event rate at 2-years was 7.9 % (57 of 720 pts); fast VT, VF or death was 18.3 % (132 of 720 pts) in ICD. Conclusions: In MADIT II, excess mortality in CONV closely paralleled the occurrence of a therapy for fast VT/VF. These data confirm that the survival benefit of ICD therapy is through reduction in death due to fast VT/VF. These data also support the potential use of therapy for fast VT/VF as a surrogate endpoint for ICD preventable mortality, and for evaluating ICD benefit in populations too small for randomized clinical trials.
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