HRS Abstract from the ALTITUDE Clinical Science Program as presented at Heart Rhythm Society Conference, May 2011; San Francisco, CA USA

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Survival After Shock Therapy In ICD And CRT-D Recipients According To Rhythm Shocked

The ALTITUDE Study Group

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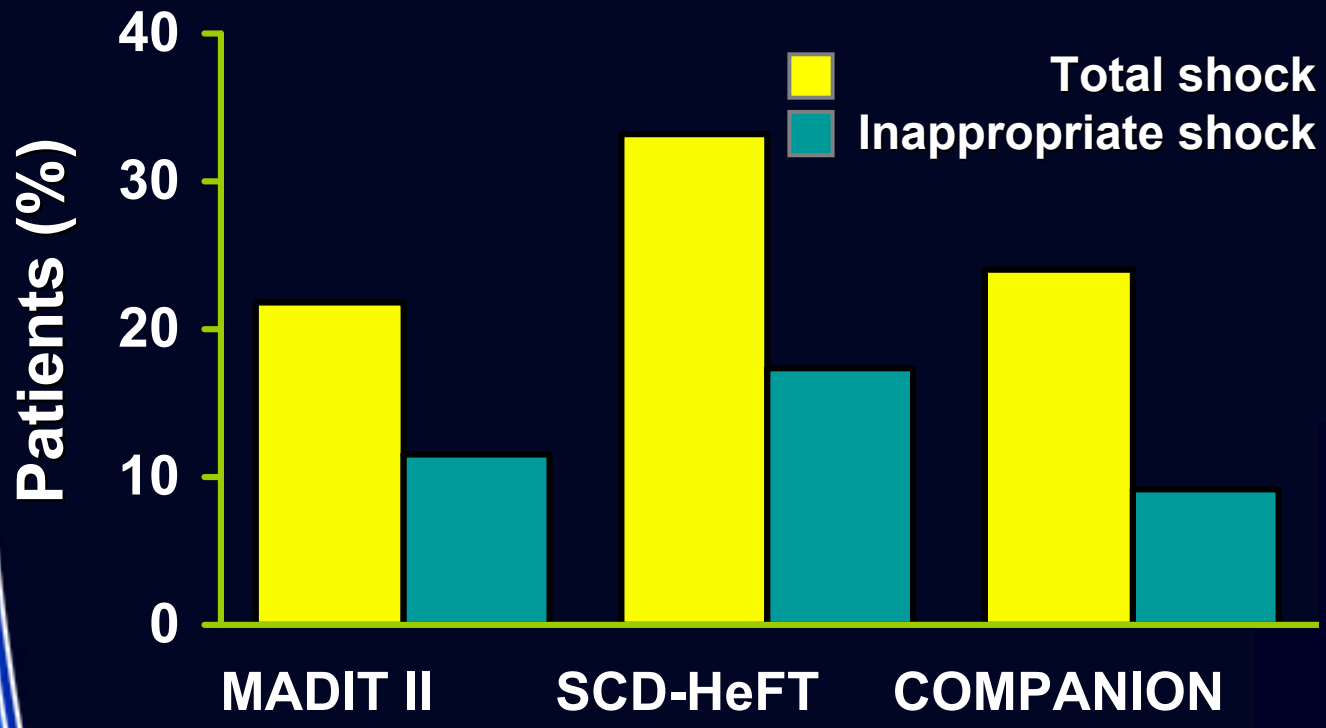
Background

- Incidence of ICD and CRT-D shocks in primary prevention trials
  - Up to 17% patients receive inappropriate shocks over 2-4 years



[1]Daubert JP et al: 51:1357, [2]Bardy GH et al: NEJM 352(3):225, 2005;
[3]Saxon et al: Circ 114:2766, 2006; *Data are for 1st shock only

Background

- Both appropriate for VT/VF or inappropriate ICD shocks are associated with an increased risk of death compared to no shocks

	Hazard Ratio of Death (95% CI)	
Study	**Appropriate Shock**	**Inappropriate Shock**
SCD-HeFT	3.0 (2.0 – 4.4)	1.6 (1.0 – 2.5)
ALTITUDE	2.5 (2.0 – 3.1)	1.5 (1.2 – 2.2)

- It is unclear why patients with inappropriate shocks have increased mortality compared to no shocks

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Objective

- We sought to determine if the increased mortality associated with inappropriate shocks is due to the underlying arrhythmia or the shock itself

Methods

- The ALTITUDE study group prospectively defined queries and study design to analyze ICD and CRT-D data transmitted through a remote monitoring system (LATITUDE®, Boston Scientific)

- 127,134 ICD and CRT-D patients
  - 28,398 patients had one or more shocks
    - Sample of 3,809 patients (13.4%) who received a shock

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Methods

- We compared patient survival by rhythm at the time of the ICD and CRT-D shock
- Two analyses methods were pre-specified
  - Analysis of time from first shock to death by rhythm at the time of shock
  - Matched pair analysis of patients with a shock to patients without a shock

ALTITUDE Adjudication Committee

Leslie Saxon, MD, ALTITUDE Chair
- University of Southern California

Brian Powell, MD, EGM Panel Chair
- Mayo Clinic

Samuel Asirvatham, MD
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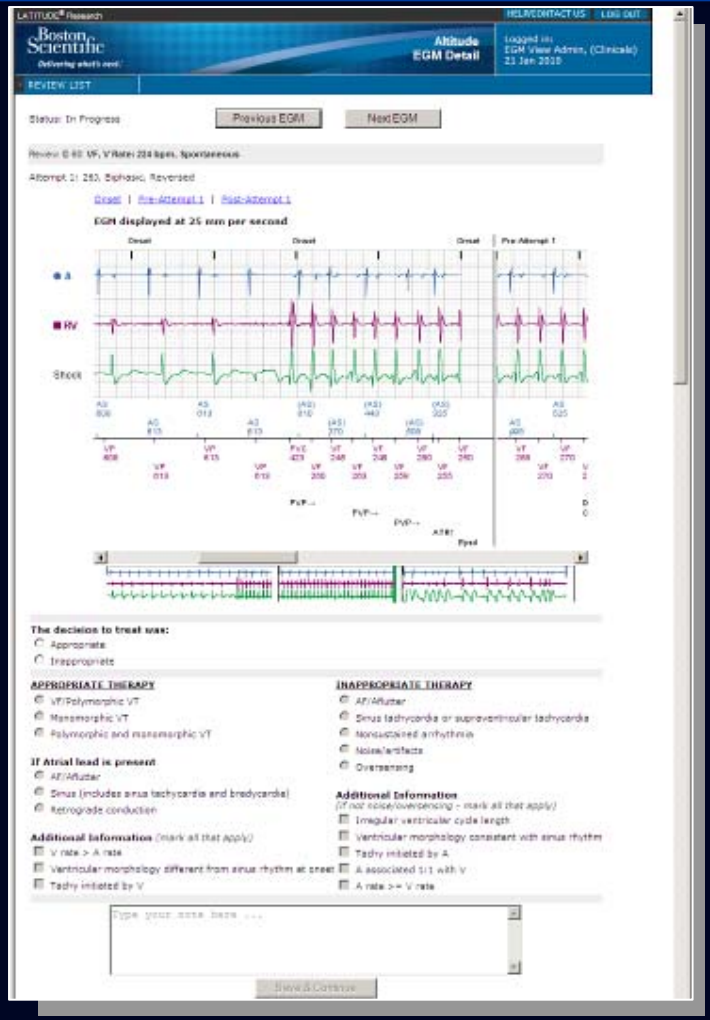
- Cardiology Associates of NE Arkansas

Soraya Samii, MD
- Penn State



ALTITUDE Adjudication Committee

Leslie Saxon, MD, ALTITUDE Panel Chair
- University of Southern California

Brian Powell, MD, EGM Panel Chair
- Mayo Clinic

The decision to treat was:

- Appropriate
- Inappropriate

APPROPRIATE THERAPY

- VF/Polymorphic VT
- Monomorphic VT
- Polymorphic and monomorphic VT

INAPPROPRIATE THERAPY

- AF/Aflutter
- Sinus tachycardia or supraventricular tachycardia
- Nonsustained arrhythmia
- Noise/artifacts
- Oversensing

F. Roosevelt Gilliam, MD
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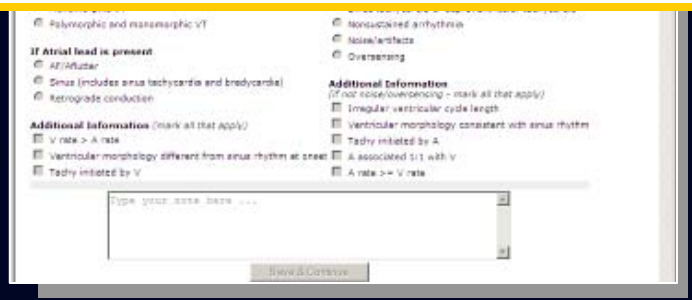

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Methods

- Survival status was obtained by cross-reference to the Social Security Death Index
- Cox proportional hazard model analysis were used to analyze time from first shock to death
  - Adjusted for age at implant and gender

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Methods

Matched Pair Analysis

- Each patient with a shock was matched to a patient who had not received a shock at the time when the first shock was delivered (3,630 patients, 95% matched)
- Patients were matched by
  - Age
  - Gender
  - Device type (ICD or CRT-D)
  - Implant year
  - Time from implant to first remote transmission

Results
Clinical Characteristics

- Patients were followed
  - 3.1 ±1.7 years from implant
  - 2.1 ± 0.4 years following a first shock

Variable	Overall	CRT-D	ICD
Number of Patients	3,809	1,541	2,268
Gender (male)	78%	79%	77%
Age (years)	64 ± 13	67 ± 12	62 ± 14

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Results

First Shock Rhythm Type

Rhythm Group	Patients n=3809 (%)	Average Age ± Std Dev (years)	Male (%)	CRT-D (%)
Monomorphic VT	1372 (36%)	67 ± 12	85%	42%
AF/AFlutter	694 (18%)	65 ± 12	77%	36%
Sinus Tach / SVT	645 (17%)	61 ± 13	74%	40%
VF/ Polymorphic VT	614 (16%)	65 ± 12	76%	43%
Polymorphic and monomorphic VT	253 (7%)	66 ± 11	80%	42%
Noise/artifact/ oversensing	178 (5%)	70 ± 11	78%	55%
Non-Sustained VT	53 (1%)	66 ± 14	74%	32%

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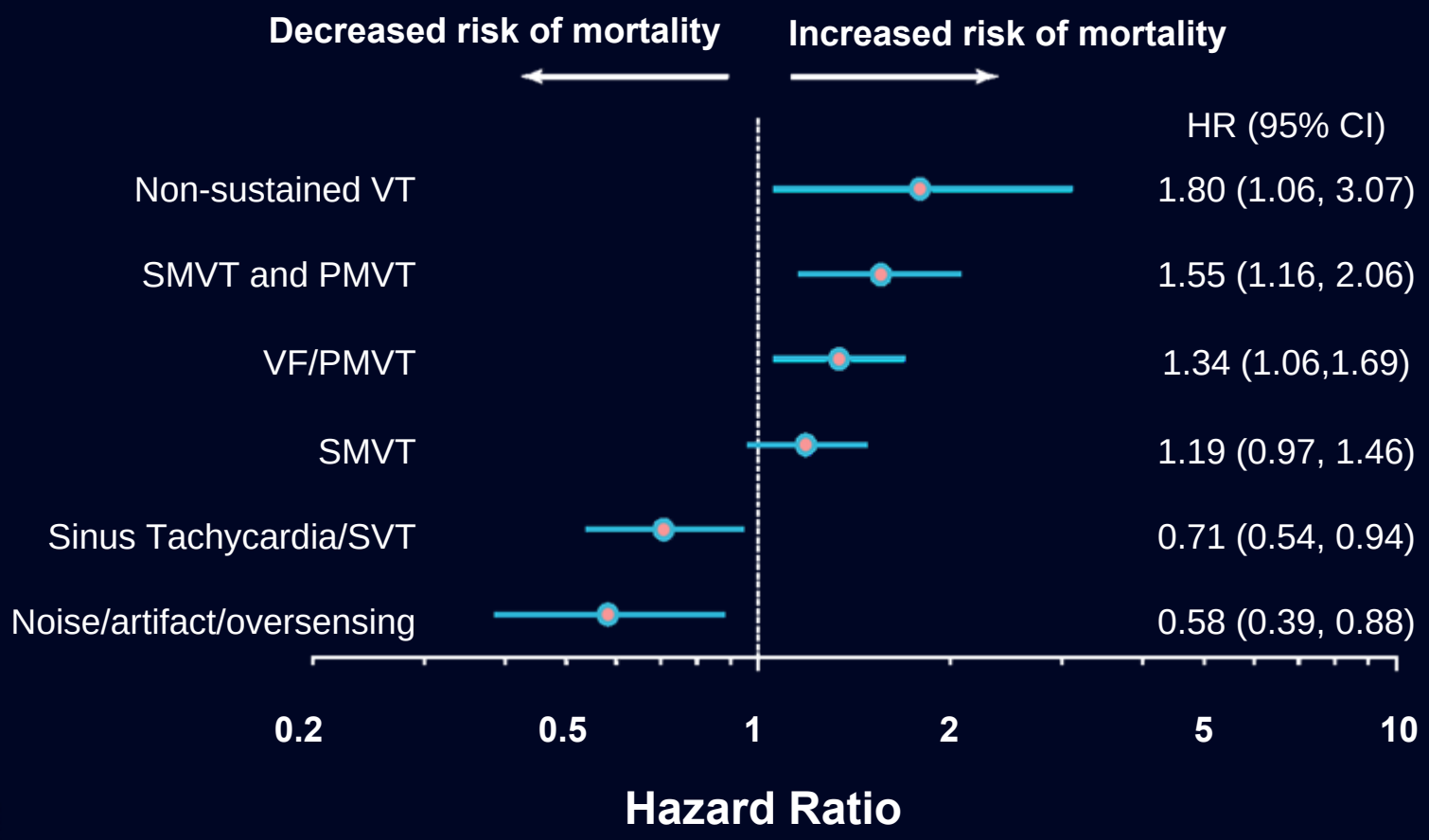
Results

Hazard of Death after First Shock

Overall ICD and CRT-D compared to AF/AFlutter



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Methods

- Non-sustained ventricular tachycardia (1% of episodes)
  - Episodes long enough to meet detection criteria and result in an ICD shock

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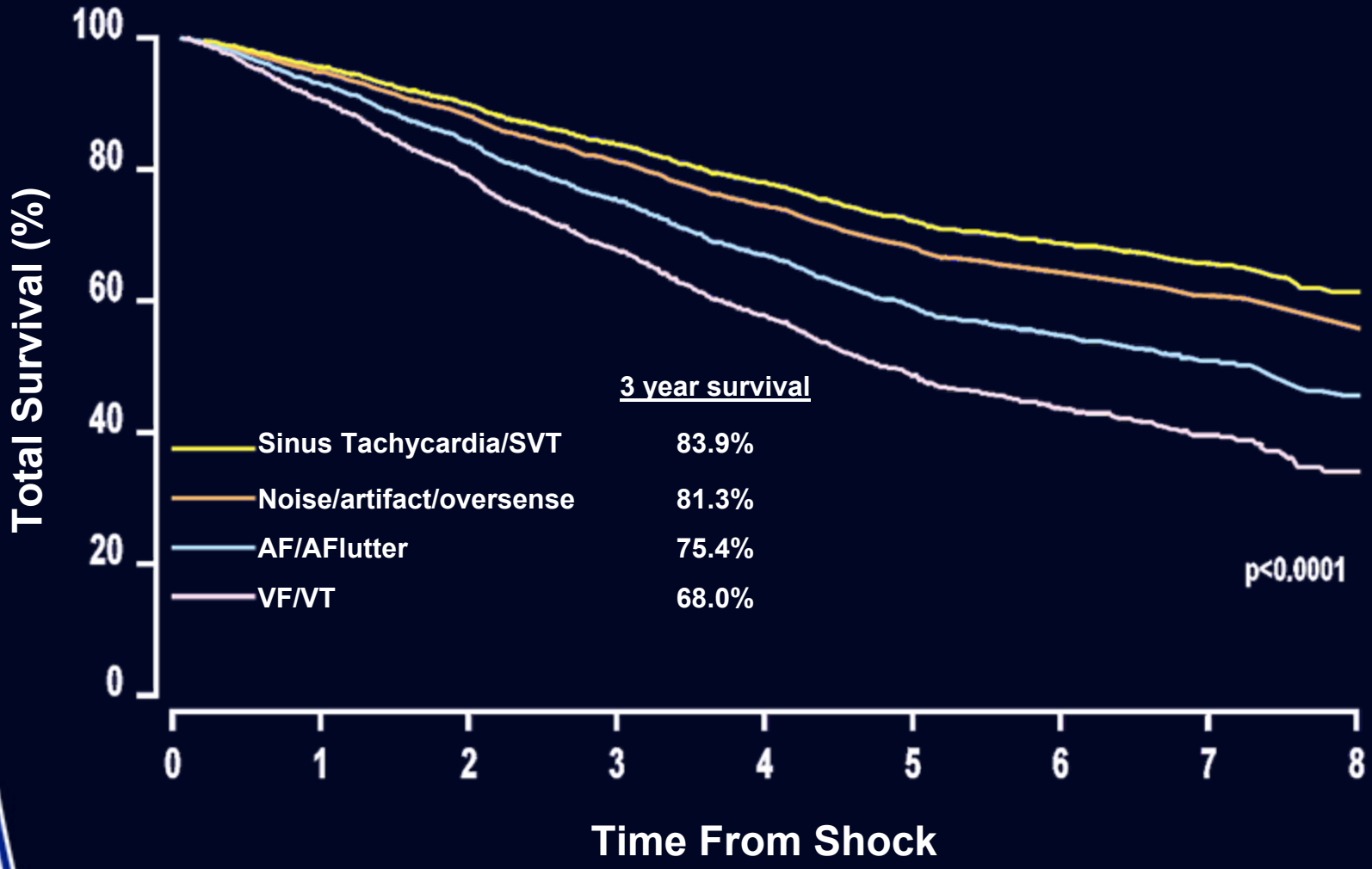
Results

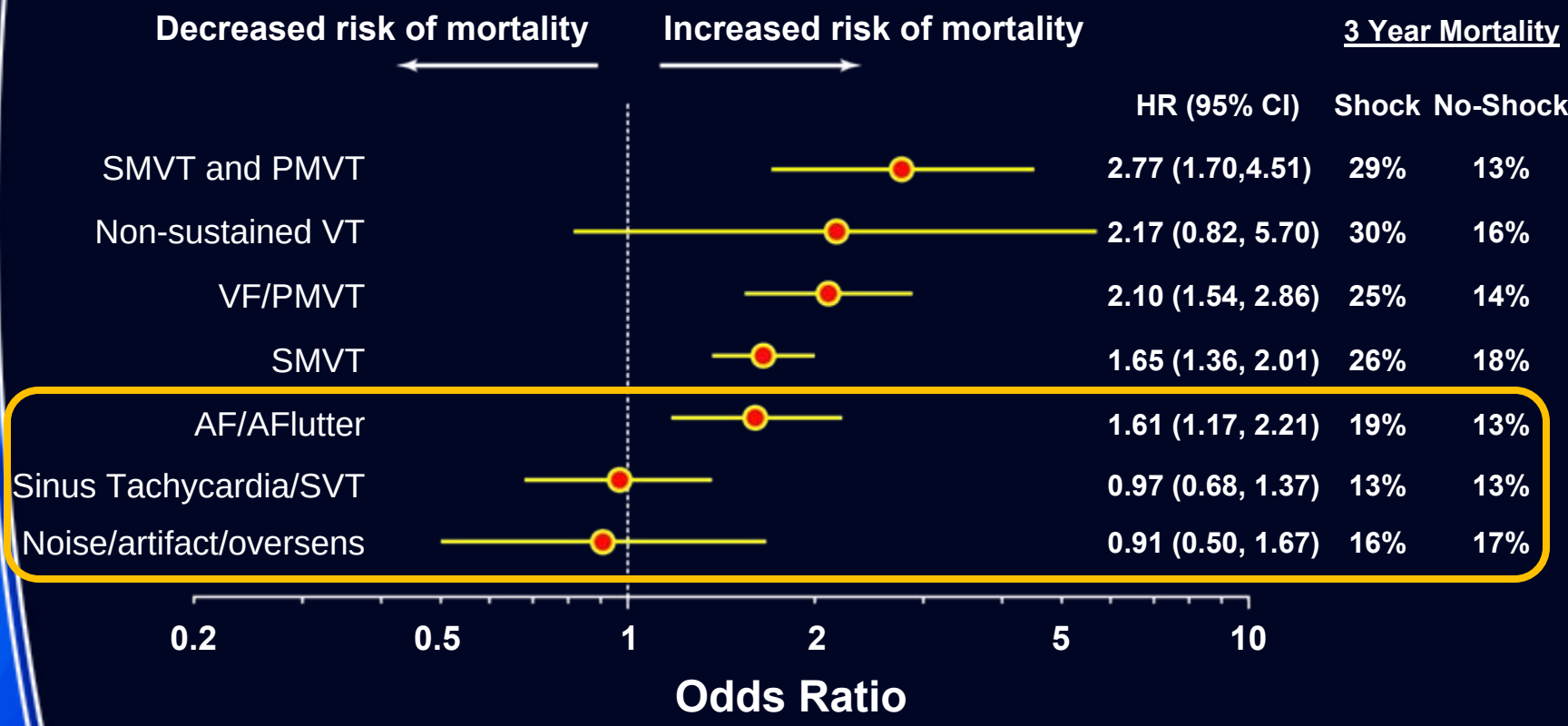
ICD and CRT-D Survival After First Shock



Results

Matched Pair Analysis

Mantel−Haenszel Odds Ratio of Death Following First Shock Compared to No−Shock Match



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Limitations

- Limited clinical data regarding co-morbidities for adjustment
- No data on medications

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Discussion

- First study large enough to analyze subgroups of patients with inappropriate shocks for different rhythms

Discussion

- Unnecessary shocks should be avoided by all available methods
  - Avoid pain from unexpected shocks
  - Patient anxiety

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Conclusions

- Patients who received inappropriate shocks for atrial fibrillation/flutter had an increased risk of death compared to no shock
- Patients who received inappropriate shocks for sinus tachycardia/SVT or noise/artifact/oversensing had no difference in survival compared to those who did not receive a shock