
Virtual ICD – What is it?

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Galileo – Dialogue on the Two Chief World Systems, 1632

- Minds are of two kinds -
 - Some adept and inclined to invent fables
 - Others disposed and accustomed to believe them
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What We Know About ICD Trials

- MADIT I – ICD's improve survival
 - MADIT II – ICD's improve survival
 - SCDHeFT – ICD's improve survival
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However,

- Reducing shocks may improve survival further (MADIT II Trial)
 - Reducing shocks improves Quality of Life (PainFREE II Trial)
 - Reducing shocks reduces morbidity – (Prepare Trial)
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MADIT II April 2008

- Patients with appropriate shocks had a higher mortality than pts without appropriate shocks
 - Patients with inappropriate shocks had a higher mortality than pts without inappropriate shocks
 - Patients with both appropriate and inappropriate shocks had the highest mortality (VF & SVT)
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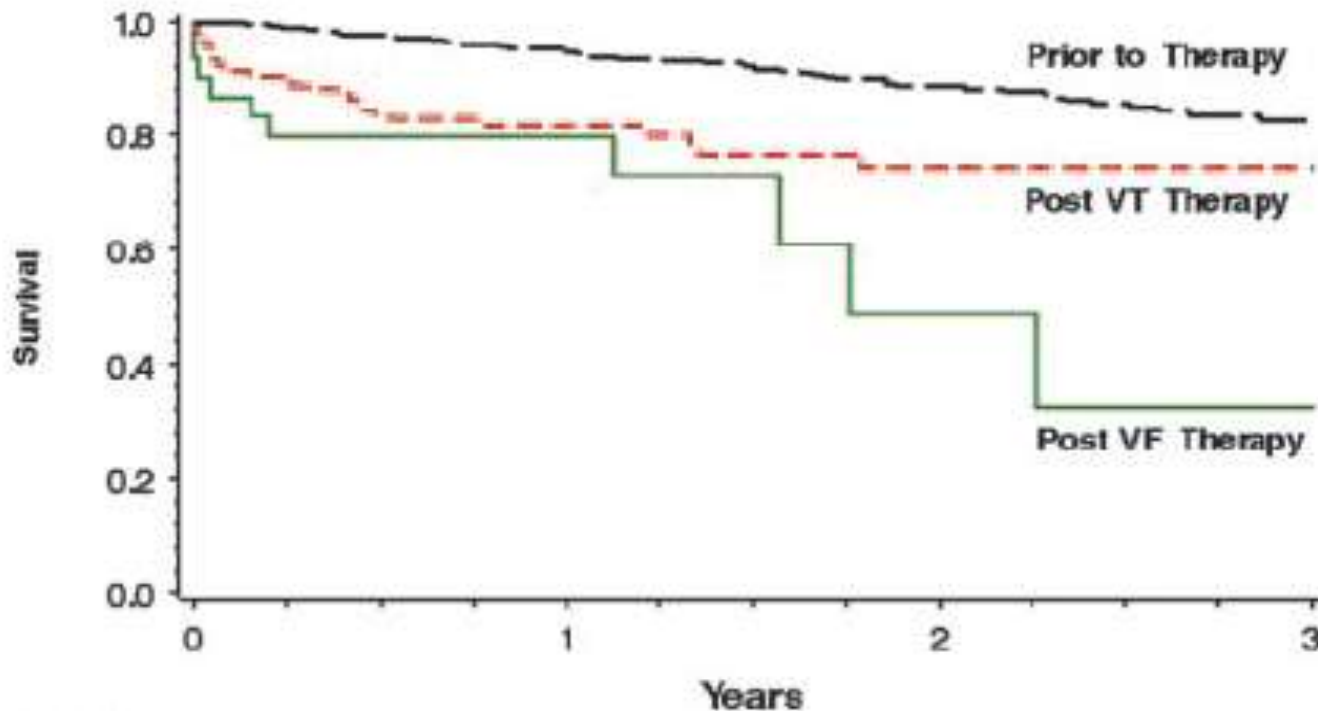
MADIT II April 2008

- What we don't know
 - Are appropriate and inappropriate shocks just a marker of a sicker population or are the shocks effecting mortality?
 - And, if we reduce the number of shocks, can we improve mortality?
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Hints – from MADIT II (April 2008)

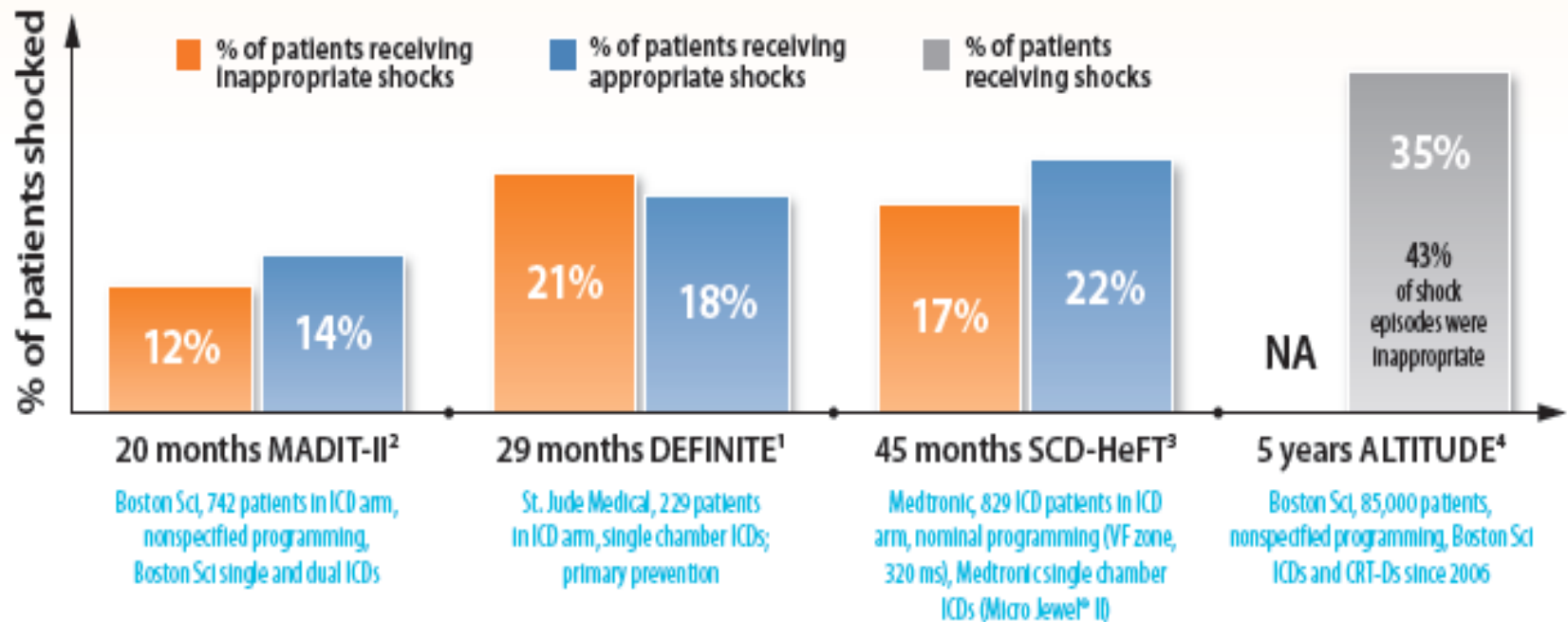
- Neither appropriate nor inappropriate ATP was associated with increased mortality
 - Pts with ‘ATP only’ events (no shocks) had an improved survival compared to pts with shocked episodes
 - So, it could be that VT/VF does not predict mortality, but shocks do.
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MADIT II: Reduced Survival After Shocks

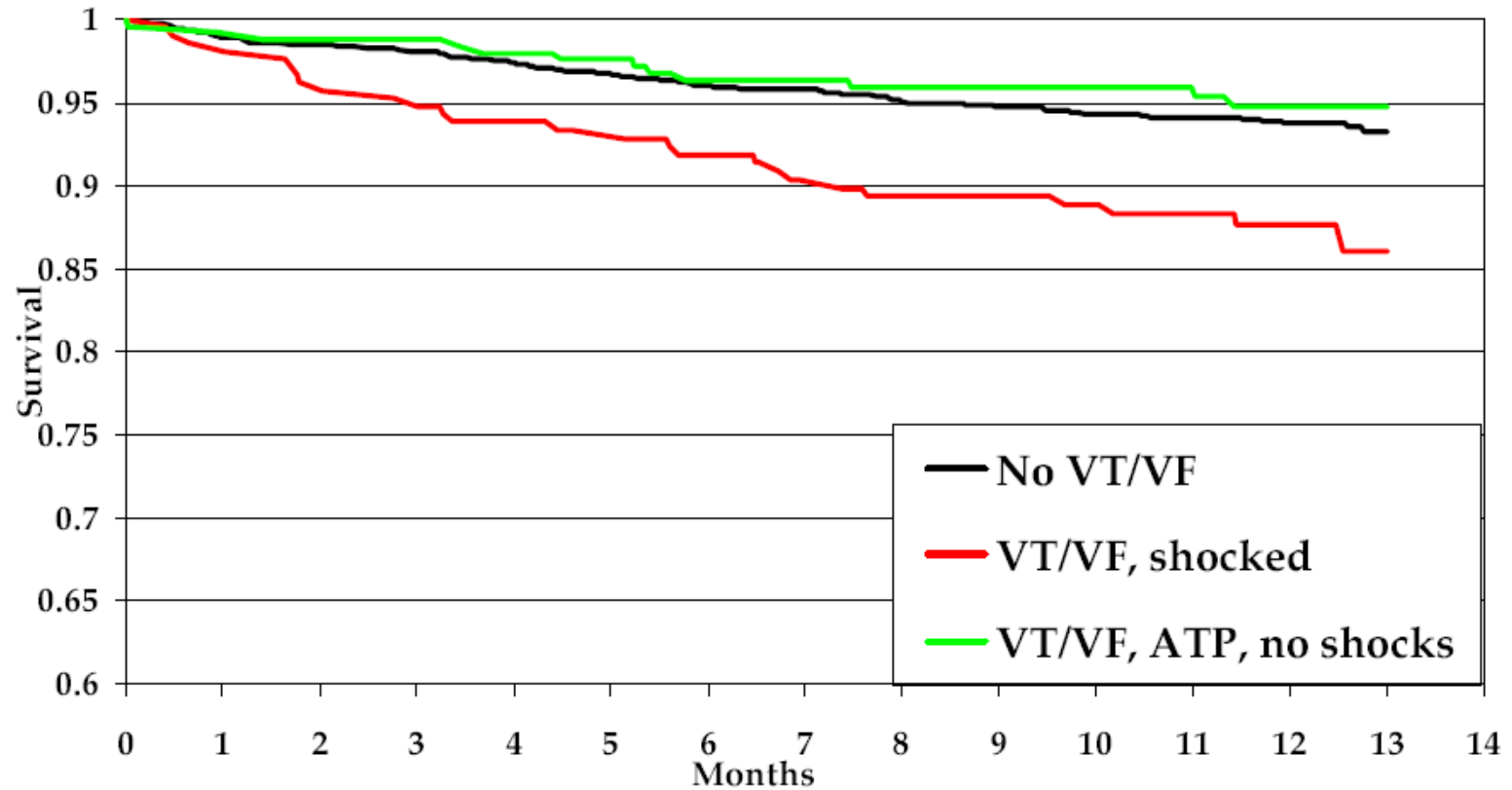


Up to 21% of ICD patients receive inappropriate shocks

Incidence of Inappropriate Shocks In the ICD Population



Strategies to minimize shocks may further improve survival of ICD patients



Why Reduce Shocks?

- Both appropriate and inappropriate shocks impact survival
 - AND quality of life
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Defibrillator Science – 3 Avenues of Research

- Randomized controlled trials – the work horse of the 80's and 90's, but incredibly slow
 - Data warehousing – such as Framingham (slow) but now ICD digital storage (such as Carelink) (fast)
 - Computer modeling – semi fast
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Virtual ICD

- Computer modeling is used in every aspect of our lives – airplanes, trains, antilock brakes, fuel injection
 - Video games
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Virtual ICD Rational

- Demonstrating improvements in ICD function requires a large number of patients to be followed for years – Prepare, Empiric, etc
 - Testing combinations of programming strategies is not feasible with prospective randomized clinical trials
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Mission

- Develop a computer model to predict the performance of multiple shock reduction algorithms and programming options
 - Must be useful for both detection and treatment decisions
 - Strive to achieve ICD optimization without the expense or patient inconvenience of multiple clinical trials
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Strategy

- Build a computer model based on data from past trials and stored real electrograms
 - Use both real and “hybrid” digital data
 - Validate the model by simulating a “real” clinical study where the results are known
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Strategy

- Then, apply the Virtual ICD model to a large contemporary database to establish clinically understandable performance predictions – in this case – we choose SCDHeFT
 - Put simply, recalculate the results of SCDHeFT episodes as if these shock reduction strategies had been used.
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Definitions

- Appropriate Shock – shock for VT/VF that would not terminate safely spontaneously or terminate with ATP
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Definitions

- Unnecessary Shock – shock for VT/VF that would terminate safely spontaneously or terminate with ATP
 - Inappropriate Shock – shock for nonVT/VF
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Strategies for Reducing ICD Shocks

- Reduce Inappropriate Shocks
 - Reduce Unnecessary Shocks
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Ways to Reduce Inappropriate Shocks

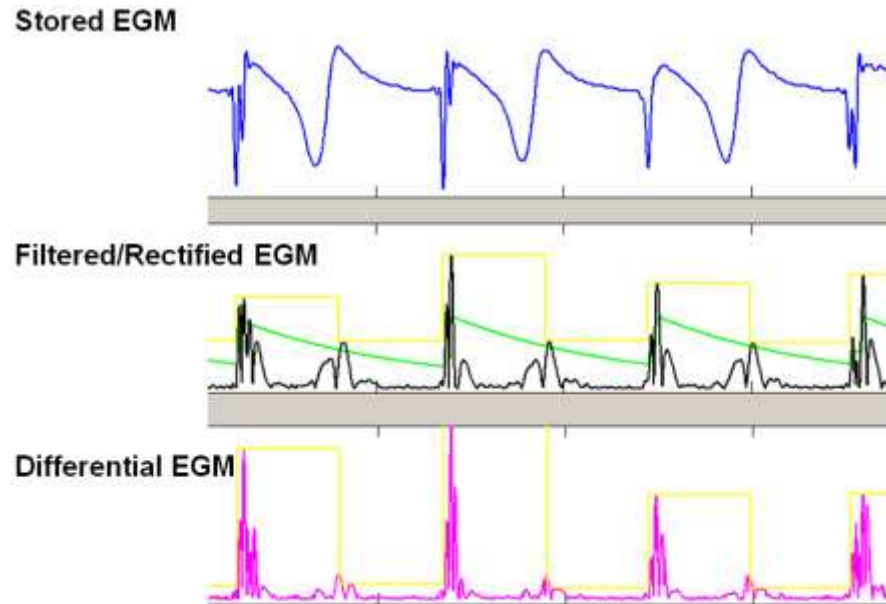
- 1. SVT Discriminators to 260 ms
 - 2. Longer Detection Time – allows more episodes to terminate spontaneously
 - 3. T Wave Discrimination – (new)
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Ways to Reduce Inappropriate Shocks

- 4. Lead Noise Discrimination – avoids shocks due to noise oversensing – (new)
 - 5. Combination of atrial and ventricular analysis (PR Logic) with EGM morphology (Wavelet) – (new)
 - 6. Tachycardia detection cut off value
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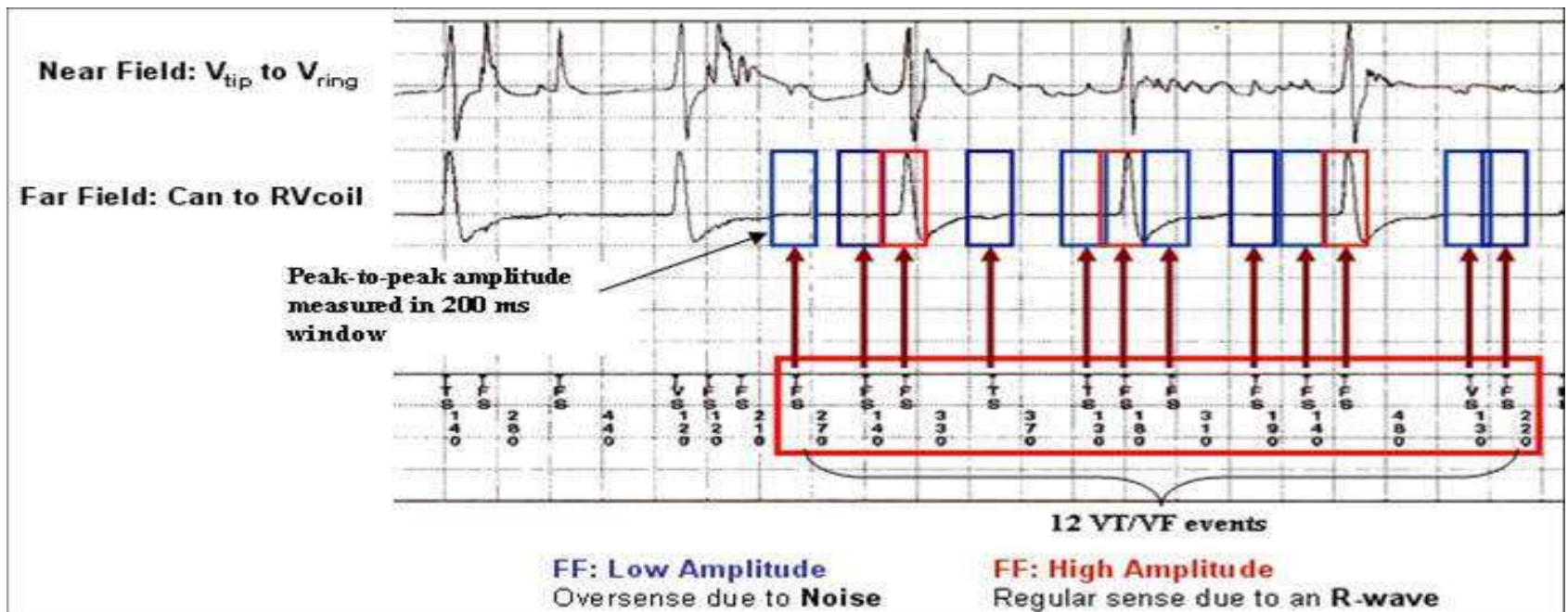
First T-Wave Discrimination

- Uses both signal frequency content and pattern analysis to distinguish R-T pattern



RV Lead Noise Discrimination

- Compare near-field sensing signal:



Virtual-ICD Challenge – Account for Multiple Episode Types

- VFib, Ventricular flutter
 - Monomorphic and polymorphic VT
 - Sinus tachycardia, atrial tachycardia, reentrant SVT
 - Atrial fibrillation and flutter
 - TWOS, lead fracture, EMI
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V-ICD Challenges

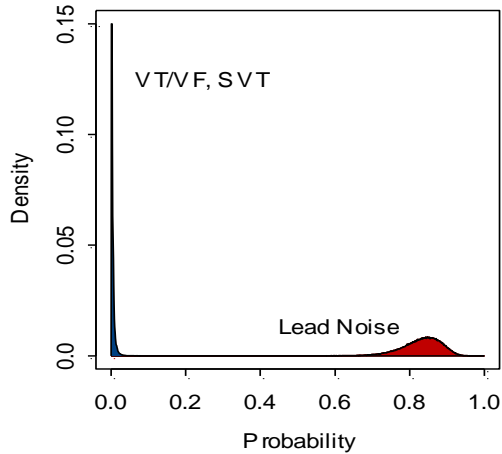
- Need to account for episode duration
 - Dual tachycardias
 - Need to have multiple algorithms process each episode
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Probabilities for the Model Decisions

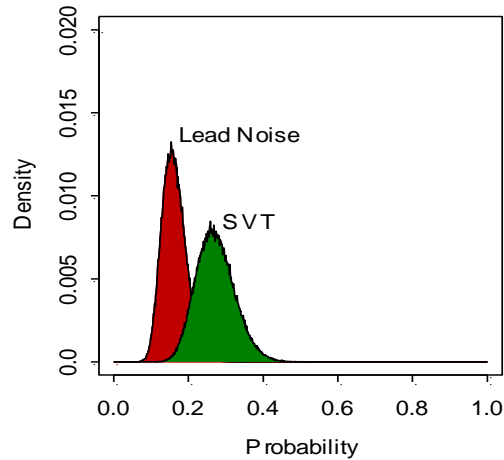
- Every possible type of episode was tested against each step in the pathway – i.e. TW discriminator during VF
 - Distributions of probable outcomes were then constructed for each step
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Probabilities for Virtual ICD

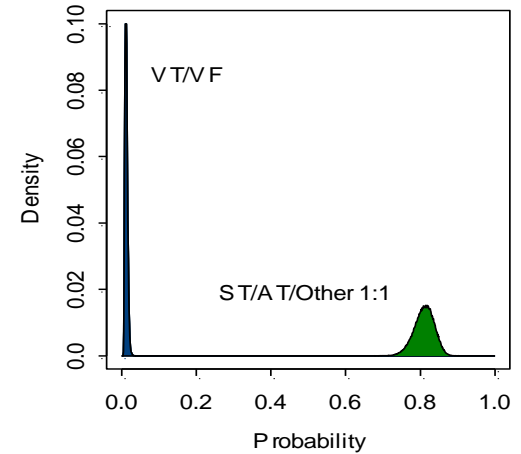
Lead Noise Withholds



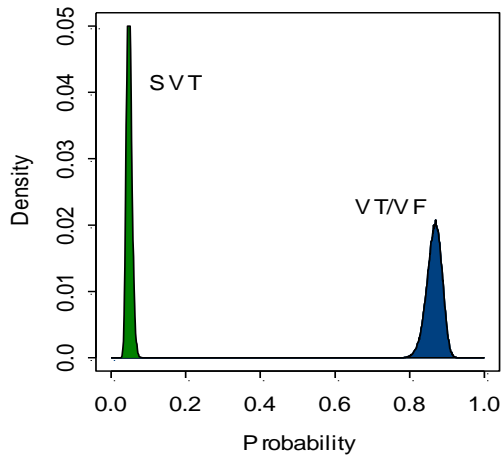
Episode Duration > 45 sec



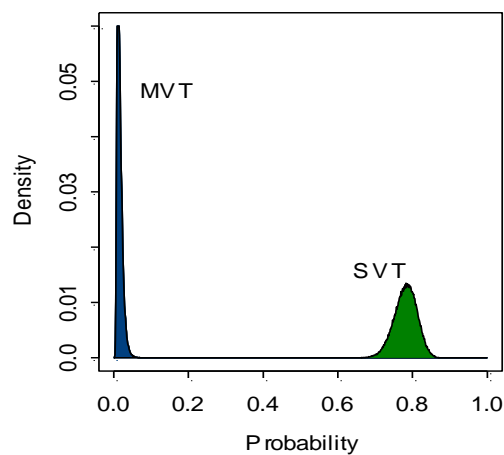
PR Logic Withholds



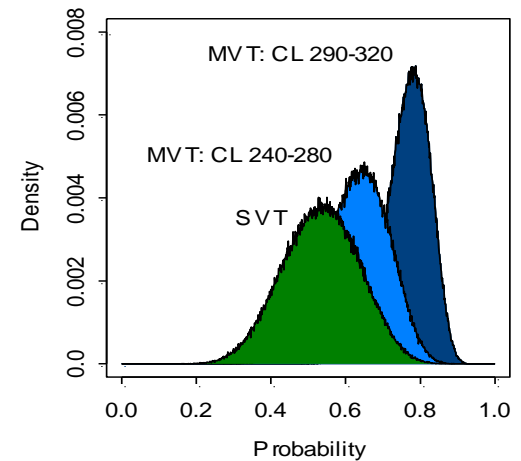
V Rate > A Rate



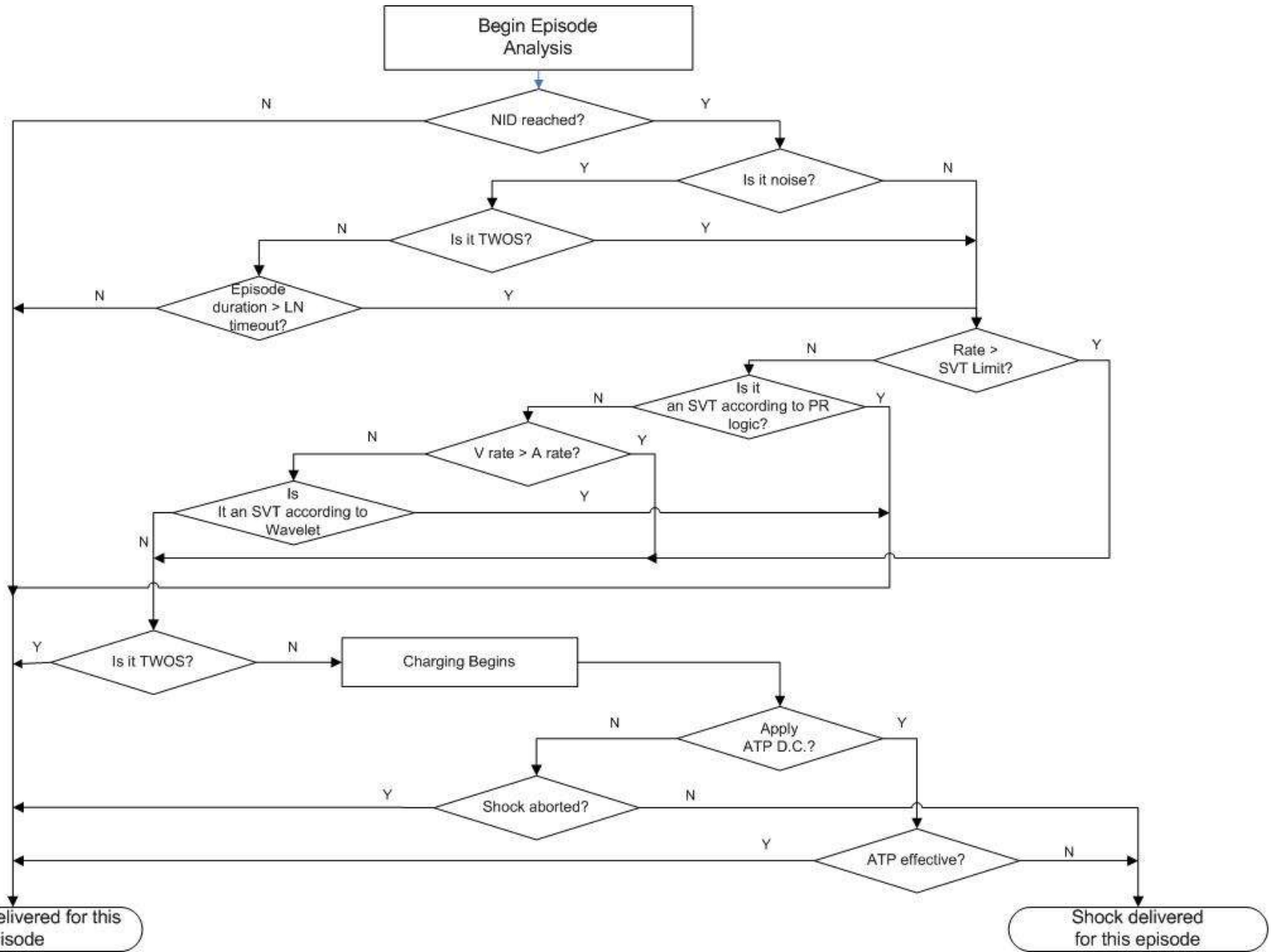
Wavelet Withholds



ATP Efficacy



Virtual ICD Decision Tree

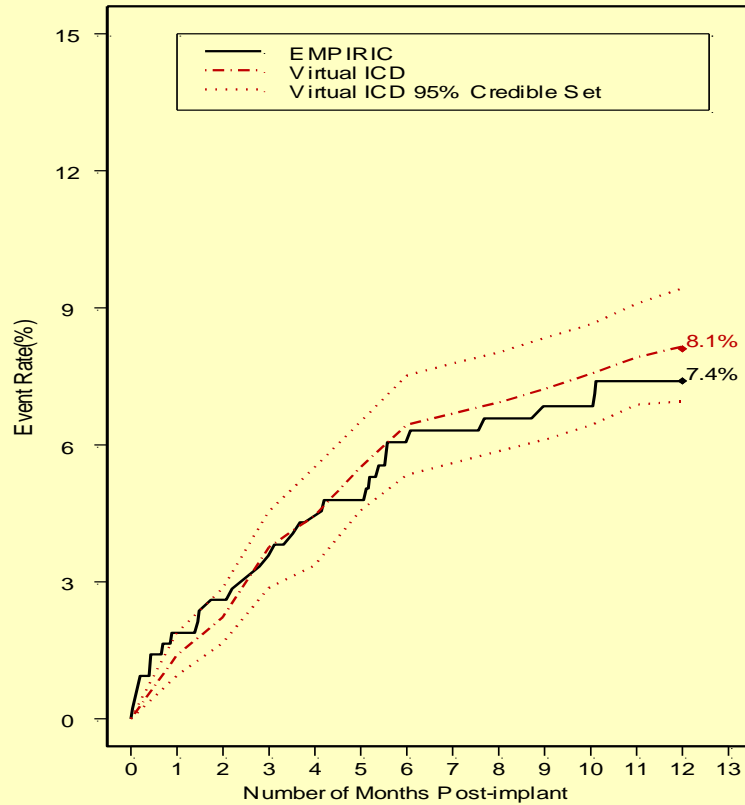


Validating the Virtual ICD – Simulate the Empiric Trial

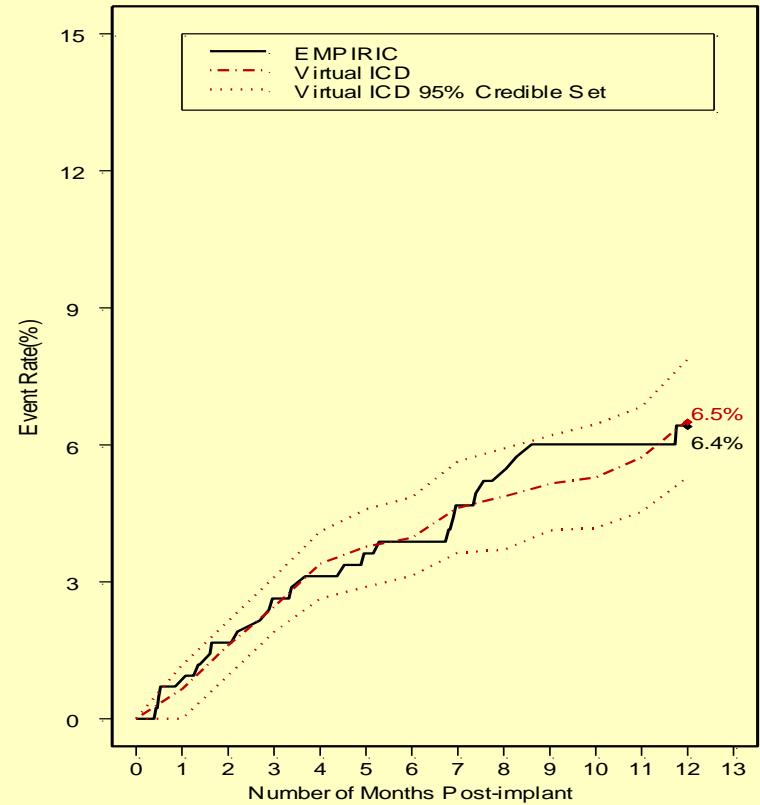
- Primary and secondary prevention patients
 - Had dual chamber ICD's
 - SVT limit at 300 ms
 - TDI at 150 bpm, VF NID=18/24
 - ATP - ON
-
- So, we set the V-ICD to these settings
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Empiric Trial Validation

First Appropriate Shock



First Inappropriate Shock



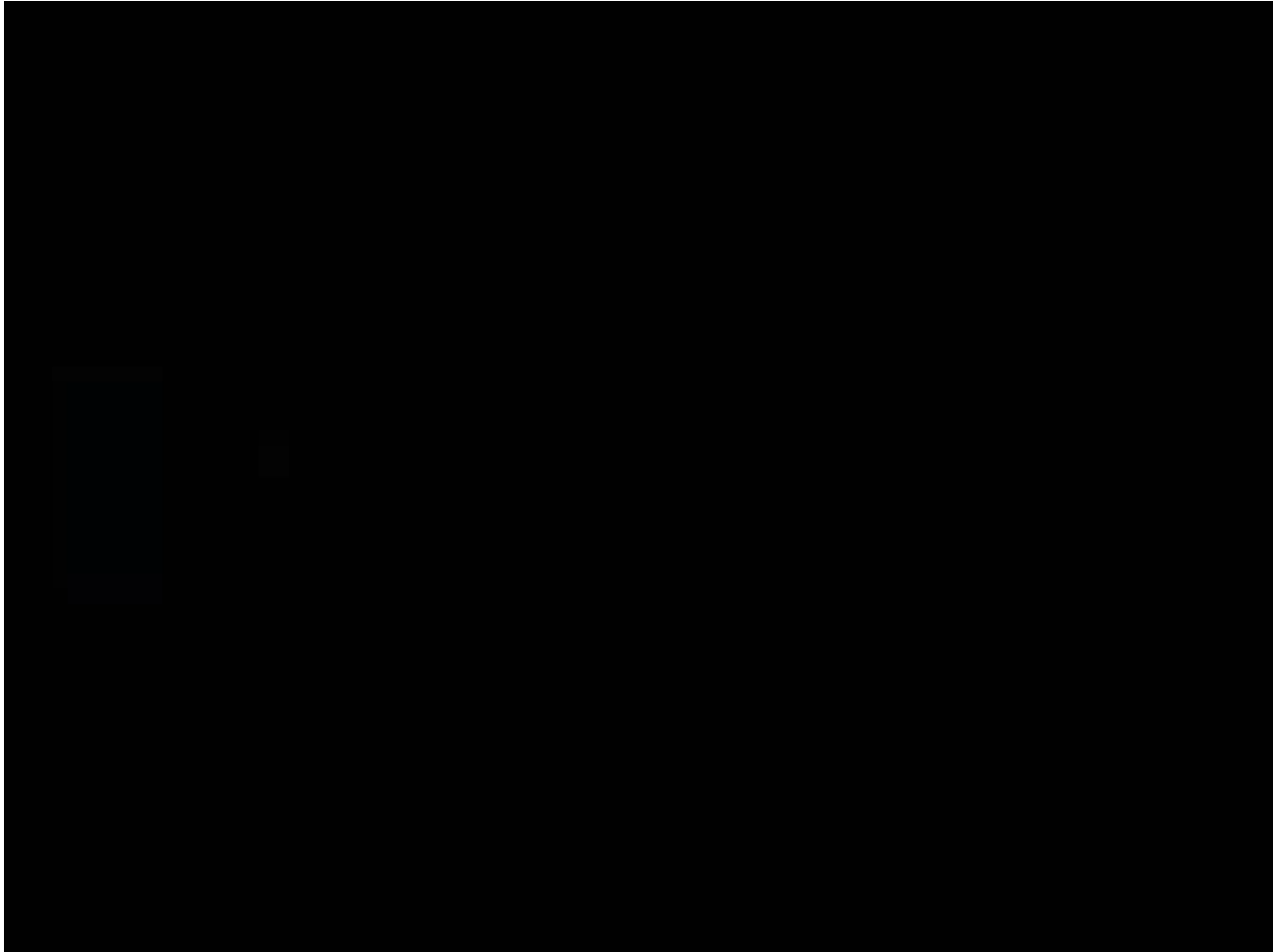
SCDHeFT Trial Episodes

- Primary prevention patients
 - Used actual electrograms from the ICD arm
 - FDI = 188 bpm, NID = 18/24
 - No ATP
 - Not all episodes from the SCDHeFT trial could be used – nonprotocol programming, not saved to disk
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SCDHeFT Simulation

- Due to the multiple probabilities involved – the SCDHeFT results were simulated by the Virtual ICD 10,000 times - to account for every possible outcome
 - Performed the simulation with NID's of 18/24 and 30/40
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Virtual ICD

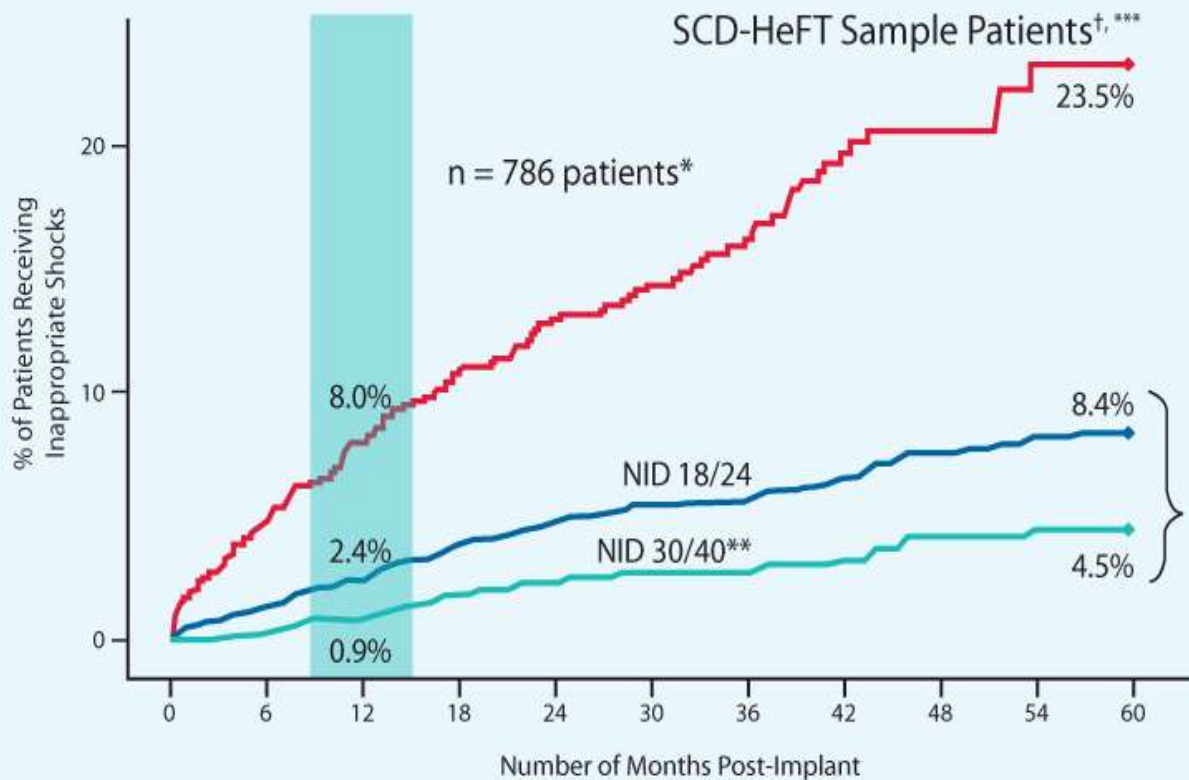


Shock Analysis – 2 Components

- Number of Patient Shocked
 - Number of Episodes Shocked
-

98% of Patients are Free of Inappropriate Shocks at 1 Year and 92% or less at 5 Years

Time to First Inappropriate Shock



† All shocked episodes from SCD-HeFT that had protocol defined programming and were determined not to be continuations of previous true VT/VF were included for these calculations (736/1,233, 59.7% of total SCD-HeFT treated episodes).

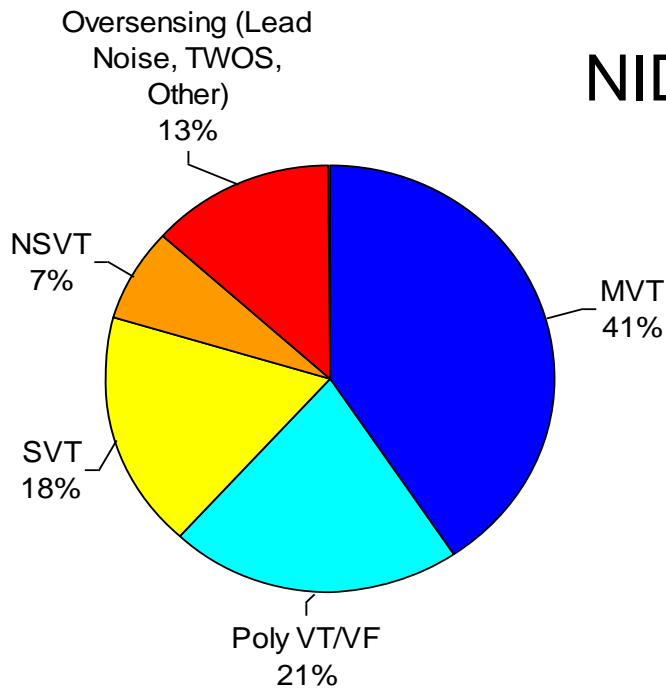
* Only the 786 subjects whose devices were initially programmed to SCD-HeFT protocol parameters were included in the analysis.

**Derived from the subset of cohort episodes (650/736) for which NID of 30/40 could be evaluated.

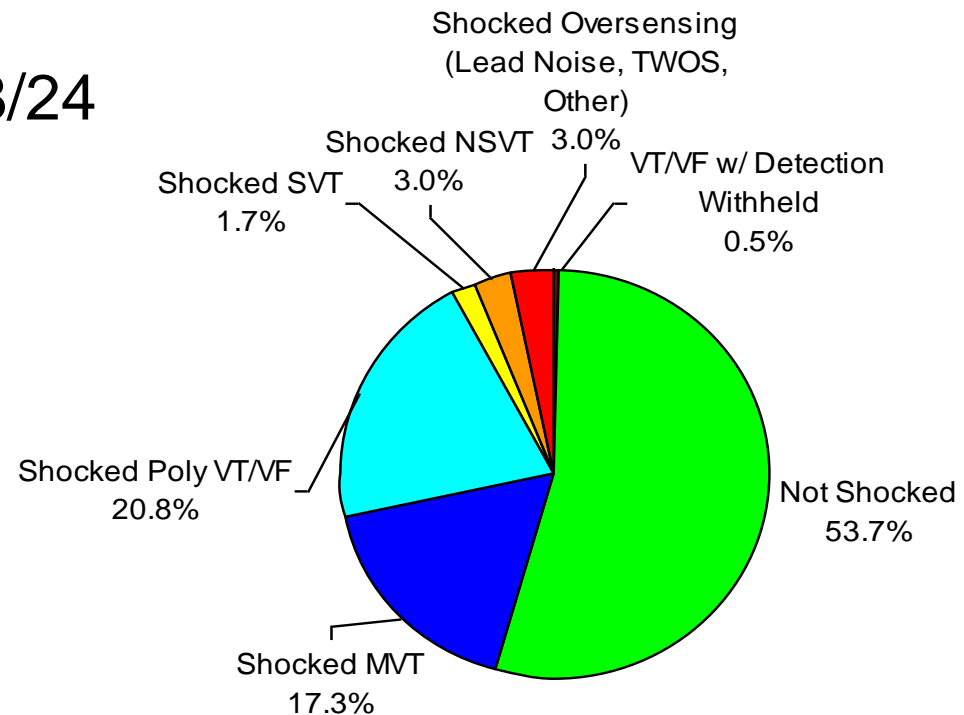
***A sample of save to disk episodes from the SCD-HeFT study was used. The analysis presented here does NOT represent the actual or official results of the SCD-HeFT trial.

Total Episode Shock Reduction: Reasons

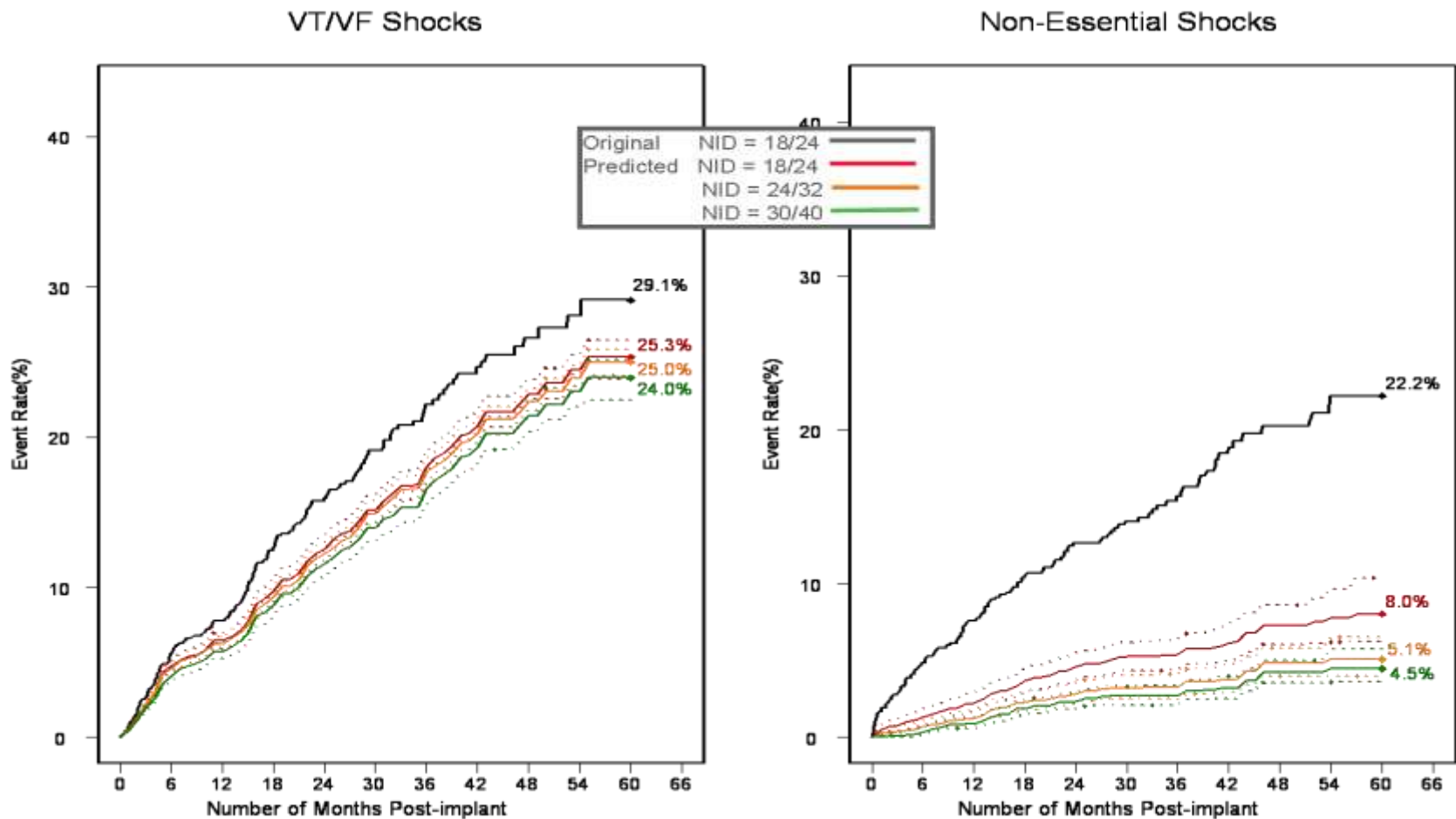
Original Programming



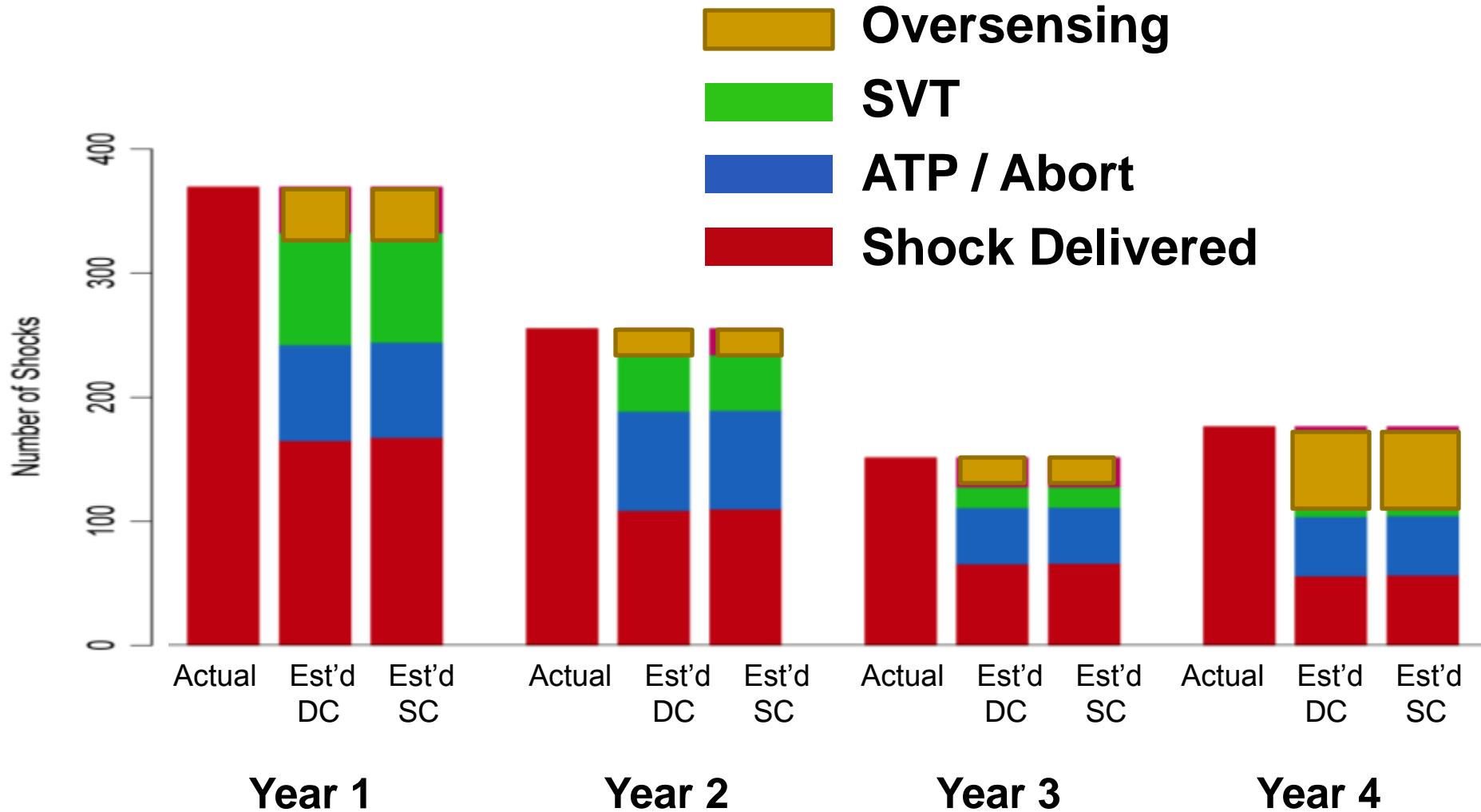
Virtual ICD Algorithms



Effect of Detection Duration on Number of Patients Shocked



Inappropriate Shock Pattern Over Time



Is it Fair to Compare Protecta with MicroJewel II?

- Consulta, Secura, Virtuoso, Maximo –
NO NEW features to reduce inappropriate shocks
 - Protecta – TW discriminator, LN Rejection, PR Logic/Wavelet and Confirmation Plus added to intelligent programming of SVT limit, ATP, detection durations
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Carelink Detection Analysis

NID*	ATP ON	SHOCK ONLY
12/16	61712 (43.2%)	19535 (63.6%)
18/24	75484 (52.8%)	10576 (34.5%)
24/32	3925 (2.7%)	488 (1.6%)
30/40	1882 (1.3%)	99 (0.3%)

Virtual ICD Conclusions

- Protecta Pts – 98% inappropriate shock free at 1 year, and 95% shock free at 5 years - as an initial programming strategy in Primary Prevention
 - V-ICD can be used for future trial design and ICD feature analysis
-



Is this the first time you realized I'm
an hallucination?