ICD Therapy: Safety features

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Objectives

- Benefits of ICD
- Predictors of ICD discharges and outcomes
- Measures to reduce ICD discharges
- Pitfalls of GD programming for VA detection
- VFTA algorithm

Benefits of ICD therapy Secondary prevention

0–2 years	2–4 years	4–6 years	6–8 years	8–10 years	10–12 years
14	24	24	17	12	12
12%	21%	21%	15%	11%	11%
4	9	5	3	4	4
12%	28%	16%	10%	12%	12%

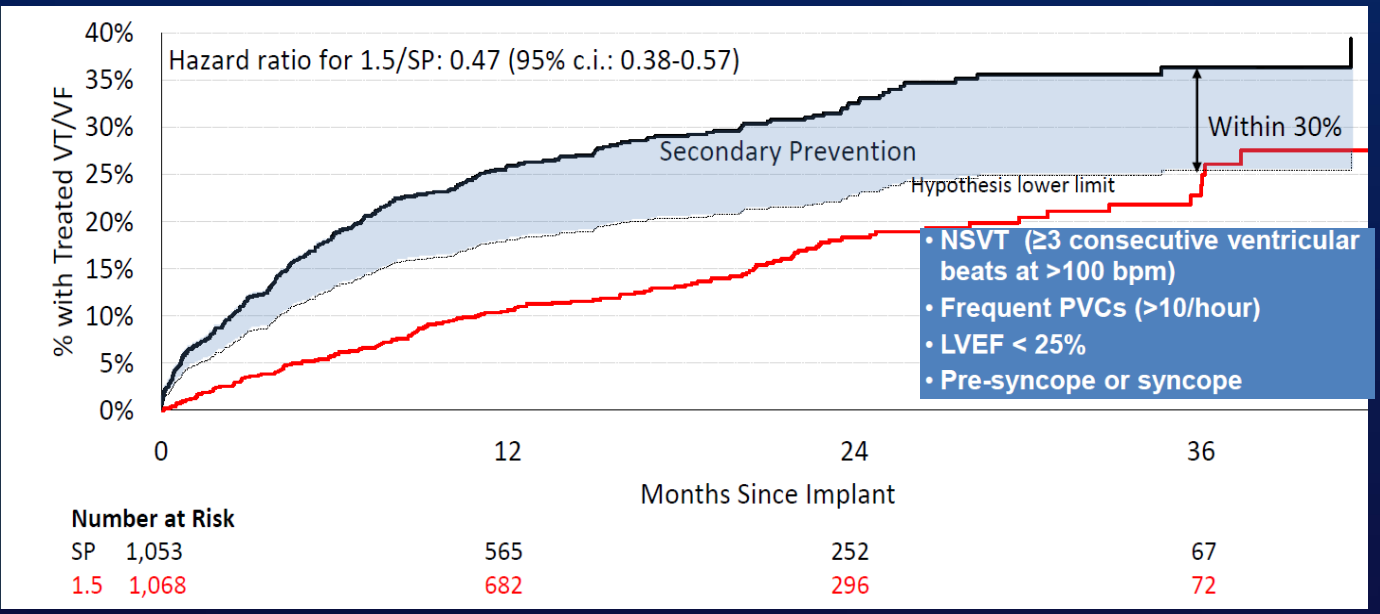
Sticherling EP Europace 2016

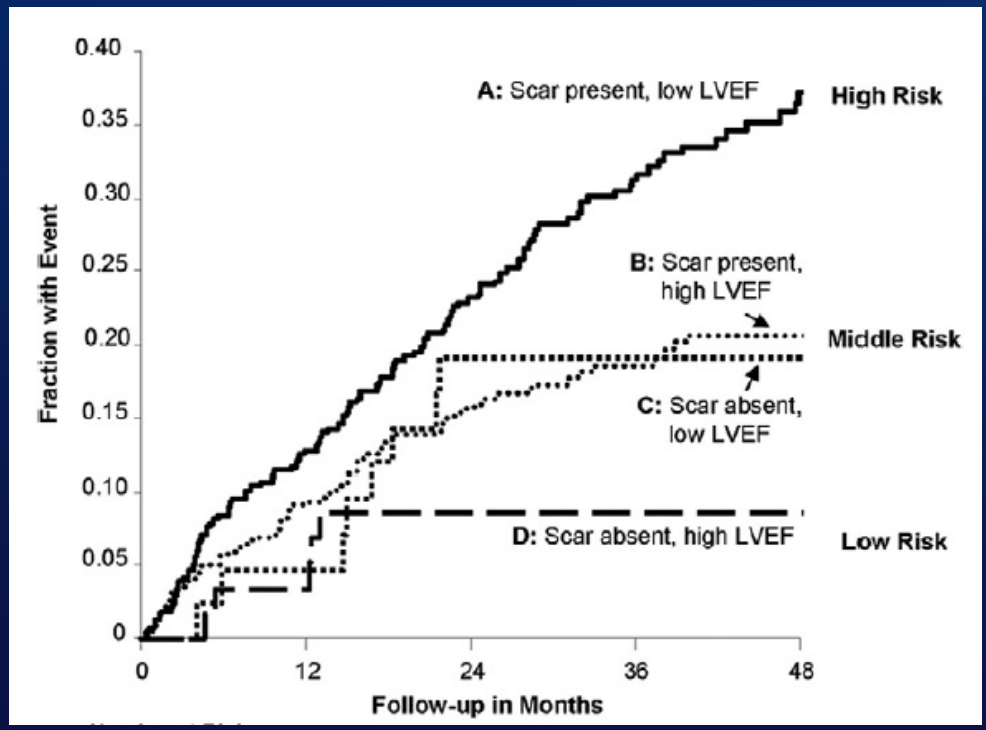
Predictors of appropriate ICD therapy

- Presence of NSVT's
- PVC Burden
- Lower Ejection Fraction
- Syncope/Pre-Syncope
- QRS Duration
- Structural Disorders (ARVC , HCM, HoCM) etc.

Predictors	Adjusted OR *	95% CI **	P Value
Male gender	2.76	1.1 – 7.1	0.021
DCM ¶ vs. CAD †	4.2	1.9 – 9.5	0.001
QRS > 100 ms	2.58	1.2 – 5.4	0.010

Indian Pacing and Electrophysiology Journal (ISSN 0972-6292), 6(1): 17-24 (2006)





Heart Rhythm. 2020 Mar;17(3):468-475. doi: 10.1016/j.hrthm.2019.09.023. Epub 2019 Sep 24

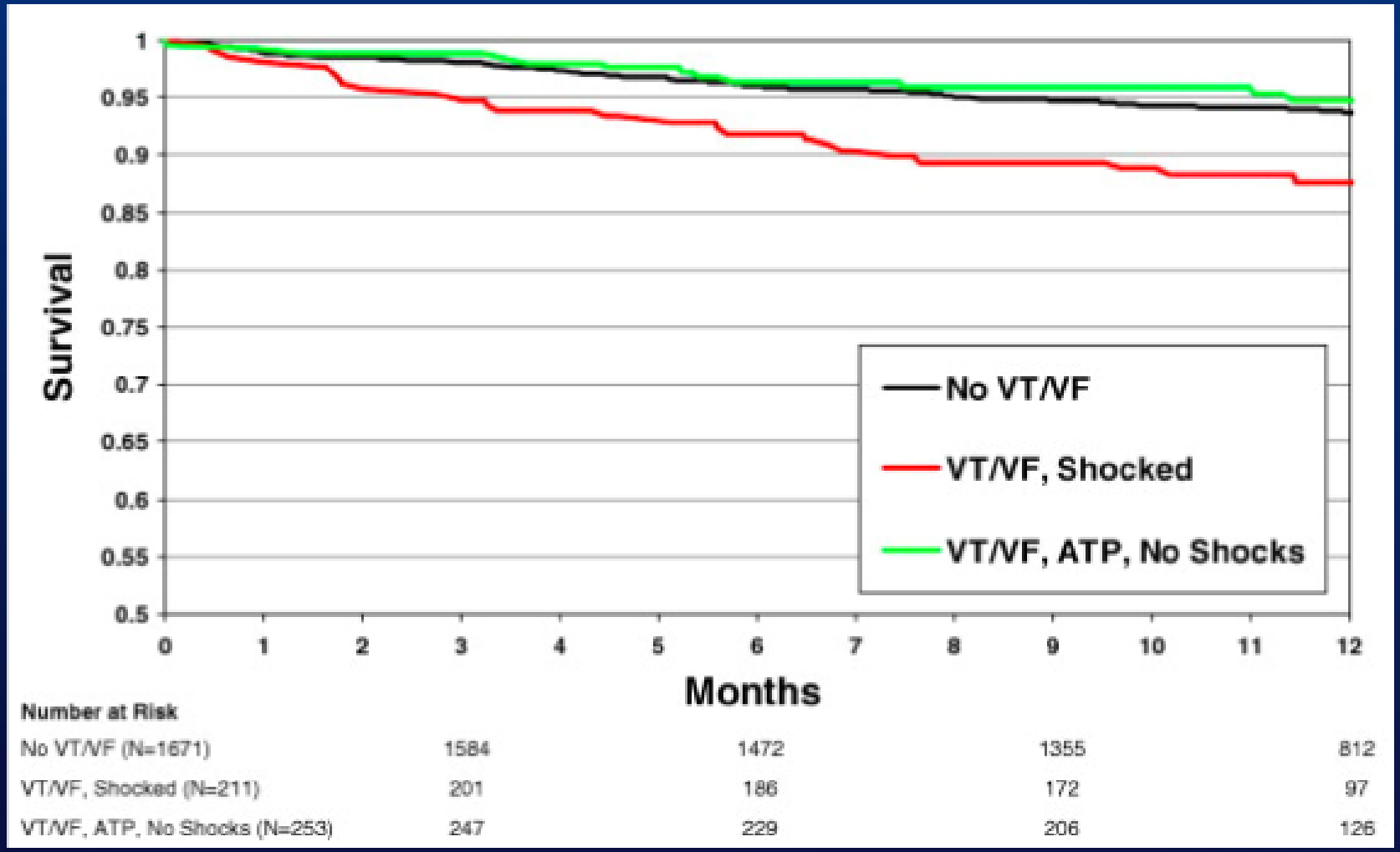
Heart Rhythm, Vol 8, No 1, January 2011

Problem statement

Type of Shock	All Patients	Patients Who Died	Time from Shock to Death			Kaplan–Meier Survival Rate 1 Year after Shock
			Median	Interquartile Range	Full Range	
			days			%
Any shock	269	77	204	1–630	0–1872	82.5±2.4
One or more inappropriate shocks only	87	10	294	28–509	0–735	94.9±2.5
One or more appropriate shocks	182	67	168	1–797	0–1872	76.9±3.2
NYHA class II	117	31	206	1–977	0–1872	84.0±3.5
NYHA class III	65	36	168	7–626	0–1343	64.2±6.1
Ischemic heart failure	93	49	96	0–443	0–1872	62.6±5.2
Nonischemic heart failure	89	18	622	204–908	1–1785	91.6±3.0
First shock for ventricular fibrillation	77	33	3	0–622	0–1872	74.6±5.0
First shock for ventricular tachycardia	105	34	258	59–797	0–1785	78.5±4.2

Wilber et al NEJM 2008

Mortality based on the type of electrical therapy



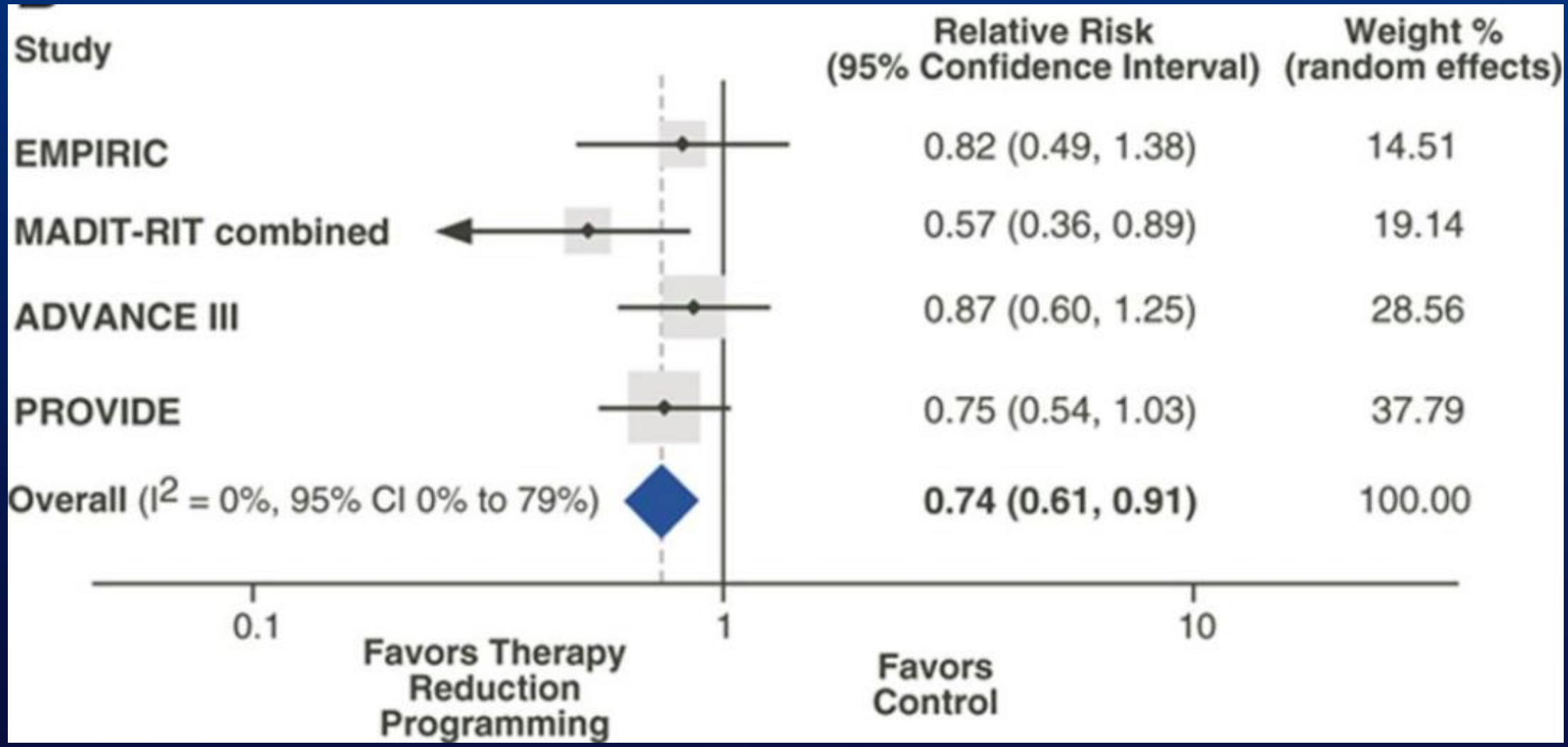
Wilkoff Heart Rhythm 2010

Solution

- *Decrease in the inappropriate shocks*
  - SVT discriminators
  - Dual chamber ICDs
  - Ablation for SVT/AF
  - Better management of HF

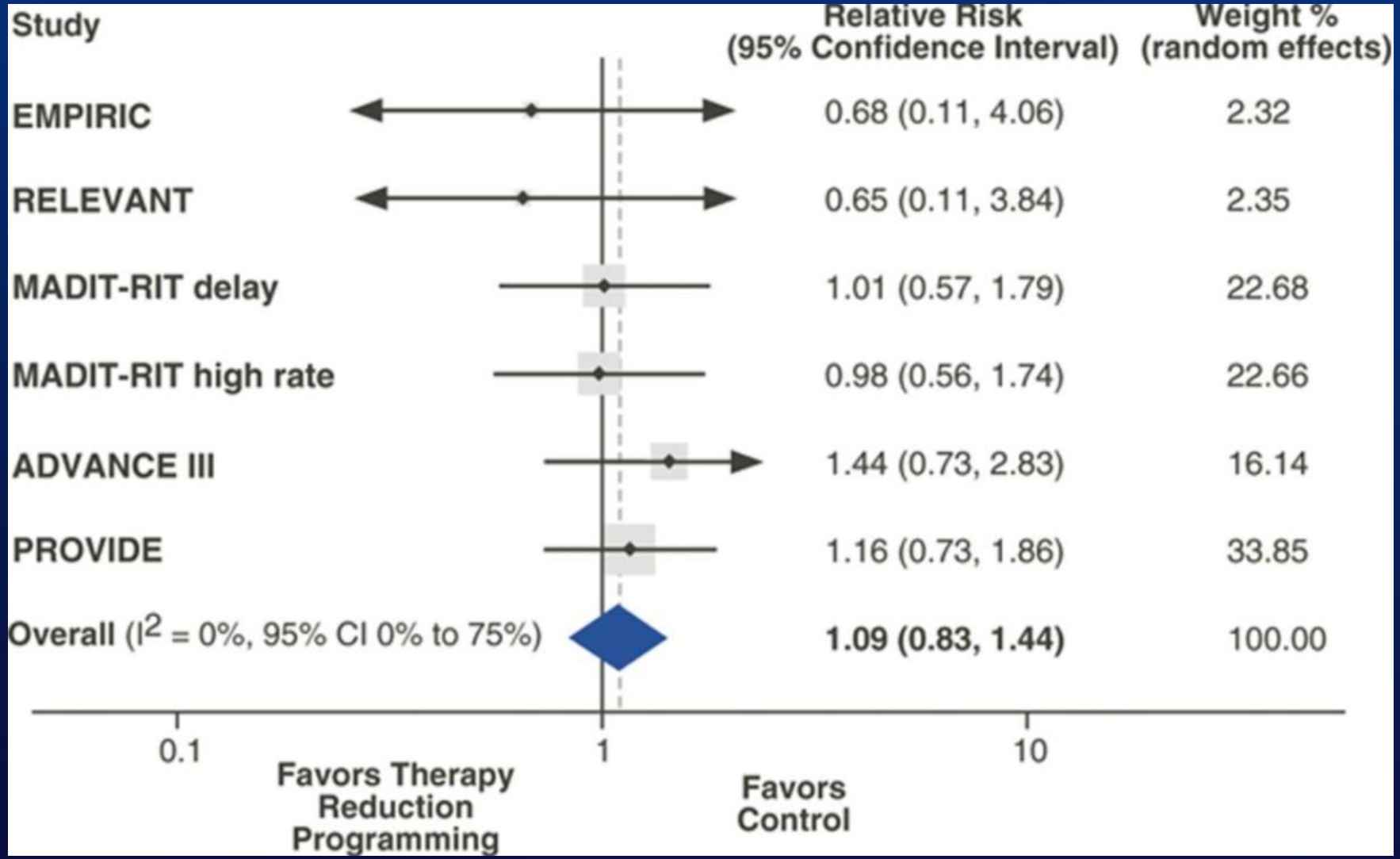
- *Decrease in appropriate shocks*
  - Promote the use of ATP
  - Use long detection intervals

Benefits of the solution Death



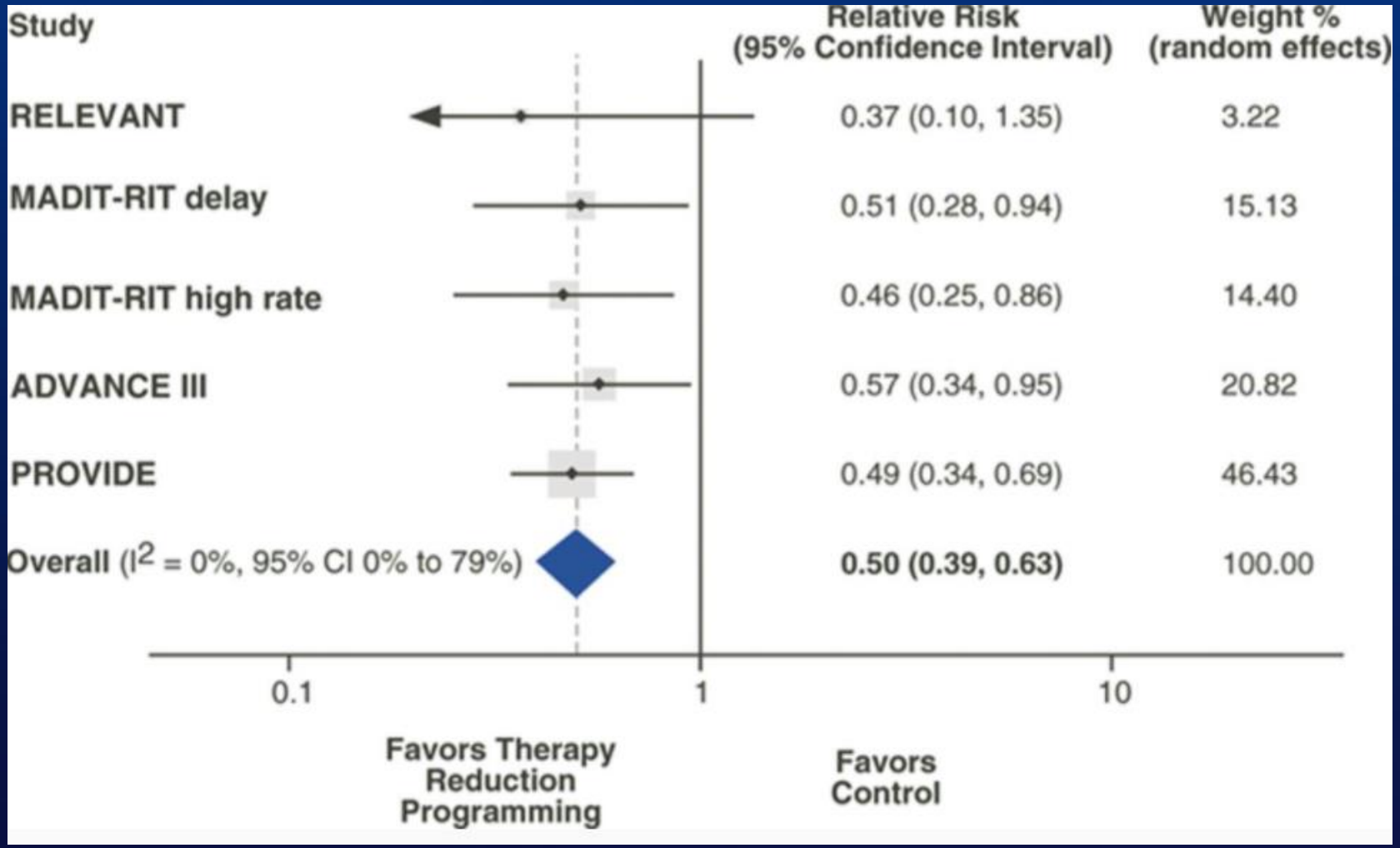
Exner et al Circ EP 2014

Benefits of the solution Syncope



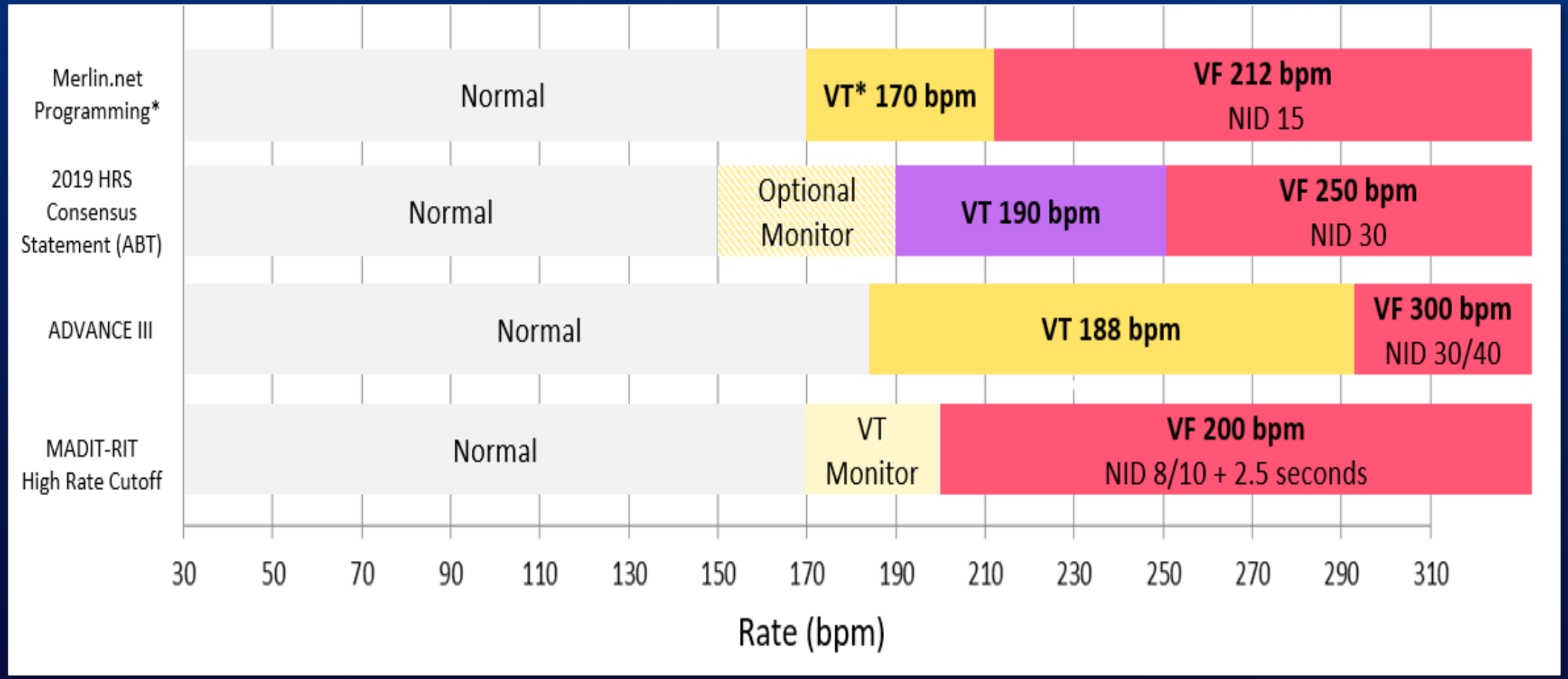
Exner et al Circ EP 2014

Benefits of the solution ICD shocks



Exner et al Circ EP 2014

Current established guidelines

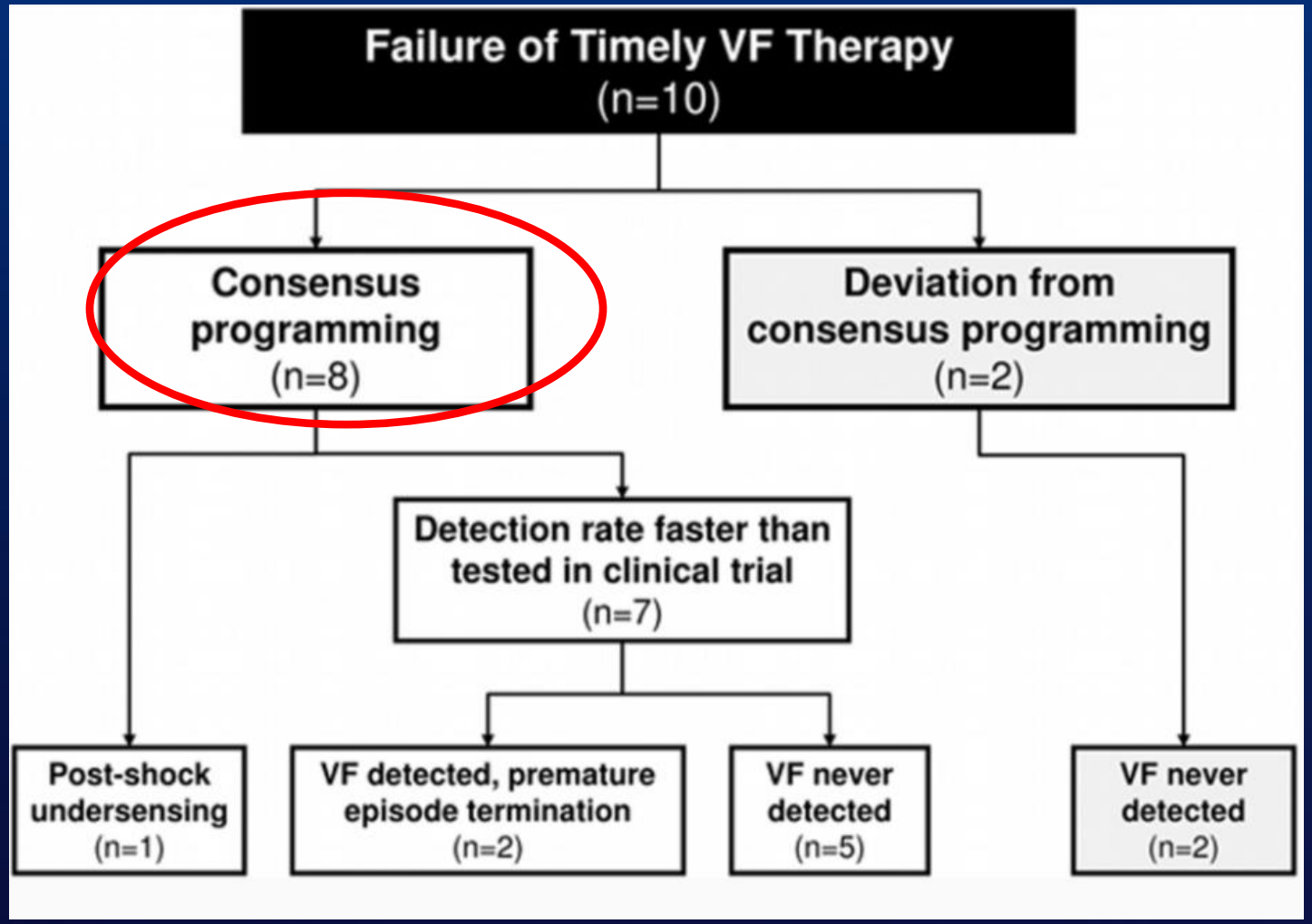


Swerdlow et al Circ EP 2017

Limitations of the duration criteria

- 477 secondary prevention patients
- MADIT RIT/RELEVANT – no single chamber ICDs
- MADIT RIT – no patients with permanent AF
- Assesses time to first therapy and not rate of therapies
- Variation in the manufacturers and detection strategies
- Control groups not programmed in a standard manner
- Rules out patients with severe illness
- Detection times plus charge times delay and effect on the therapies

Clinical outcomes of the pitfalls



Swerdlow et al Circ EP 2017

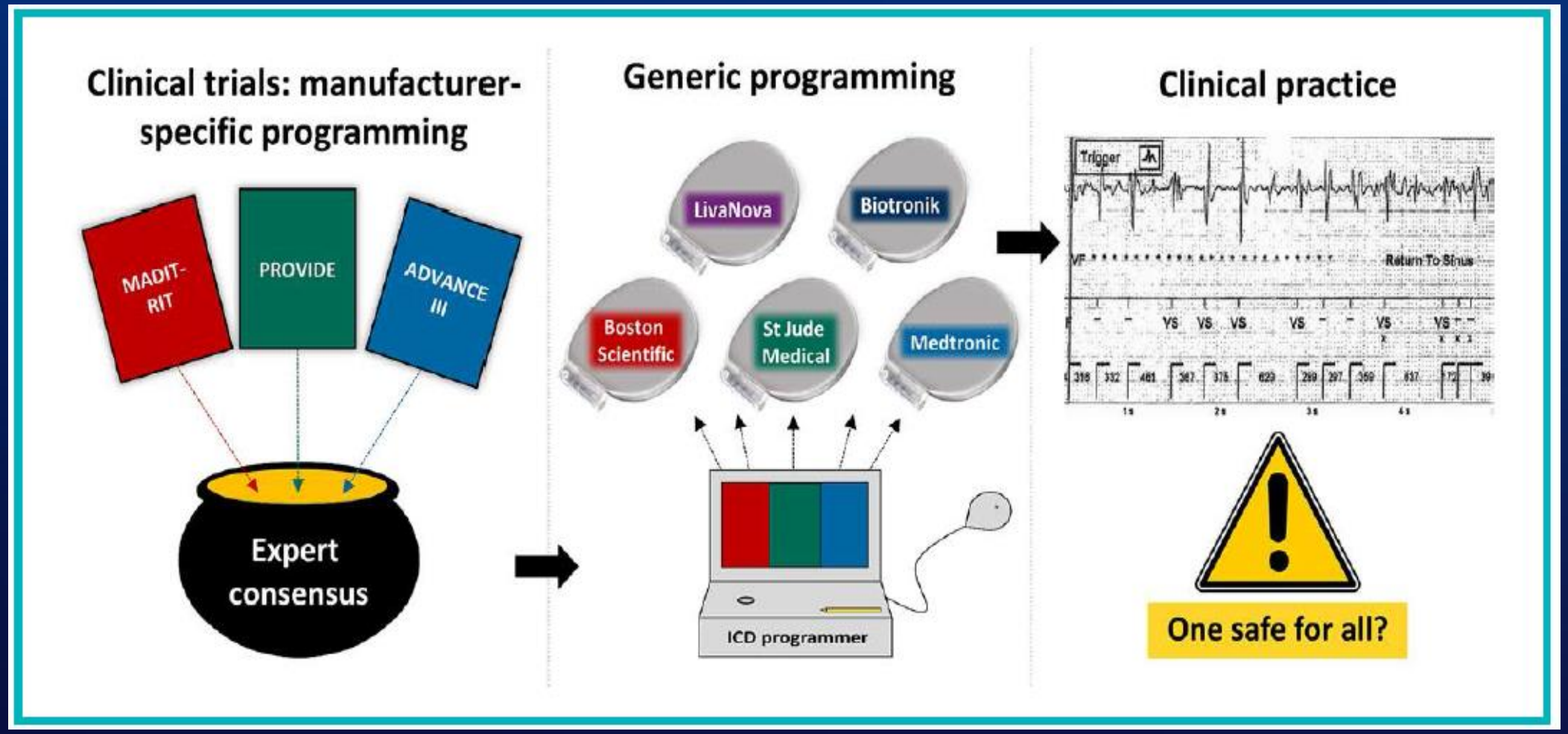
(1) a shock for life-threatening VT/VF was either not delivered or delayed significantly, resulting in death or a major adverse event

(2) The ICD system functioned normally

(3) VT/VF detection and therapies were programmed ON

(4) Sinus R waves Amplitudes exceeded 5 mV at implant and follow-up. Index events occurred from April 2015 to January 2017

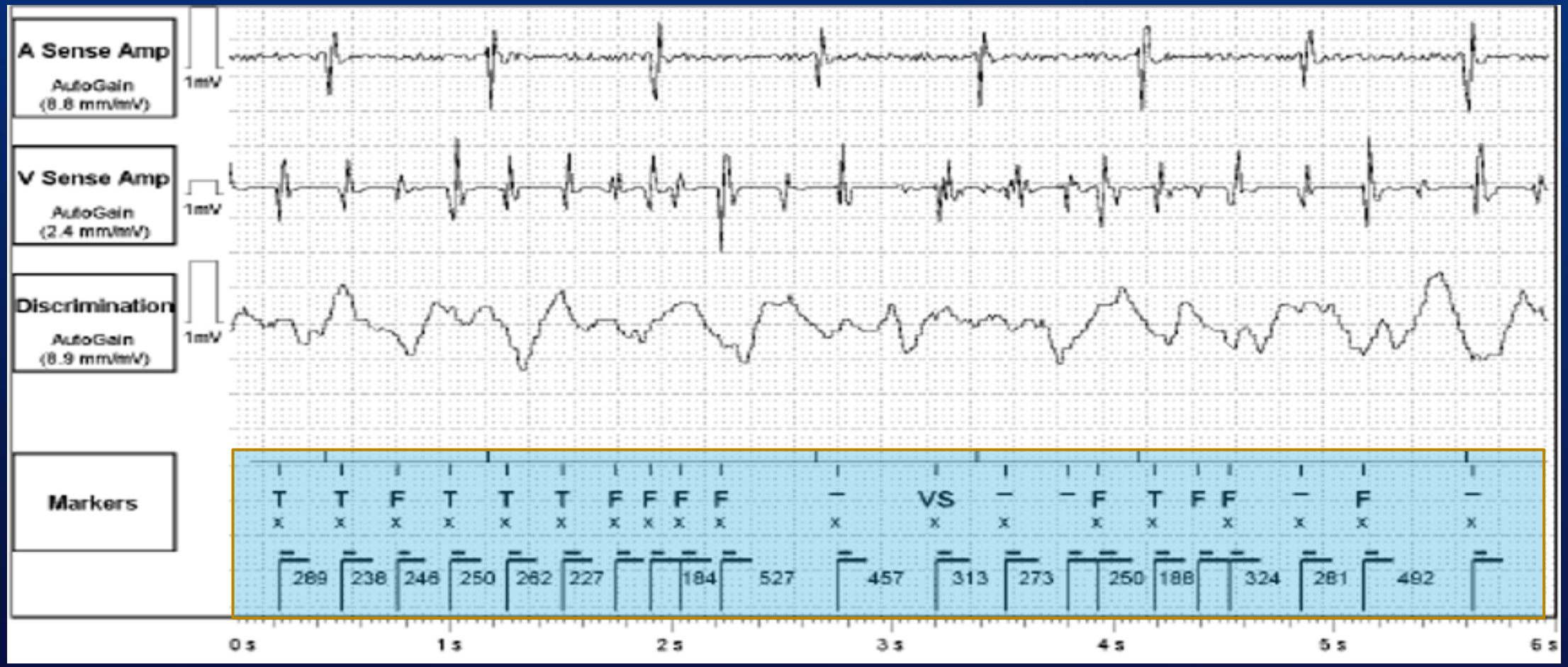
BAD IS GOOD AND GOOD IS BAD??



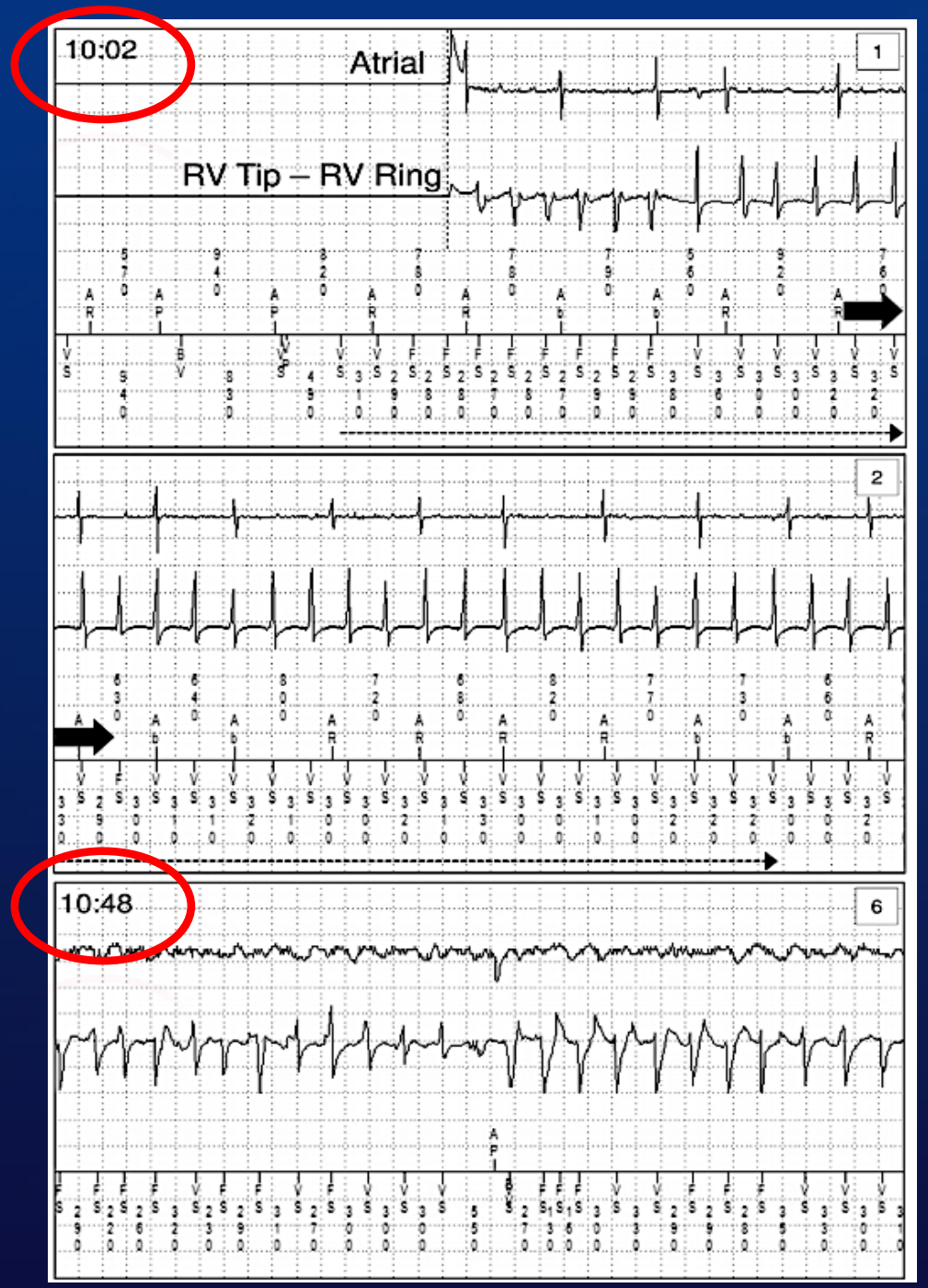
Swerdlow et al Circ EP 2017

The sad truth is that it is the greatest happiness of the greatest number that is the measure of right and wrong.
—Jeremy Bentham

Tachycardia Toggling



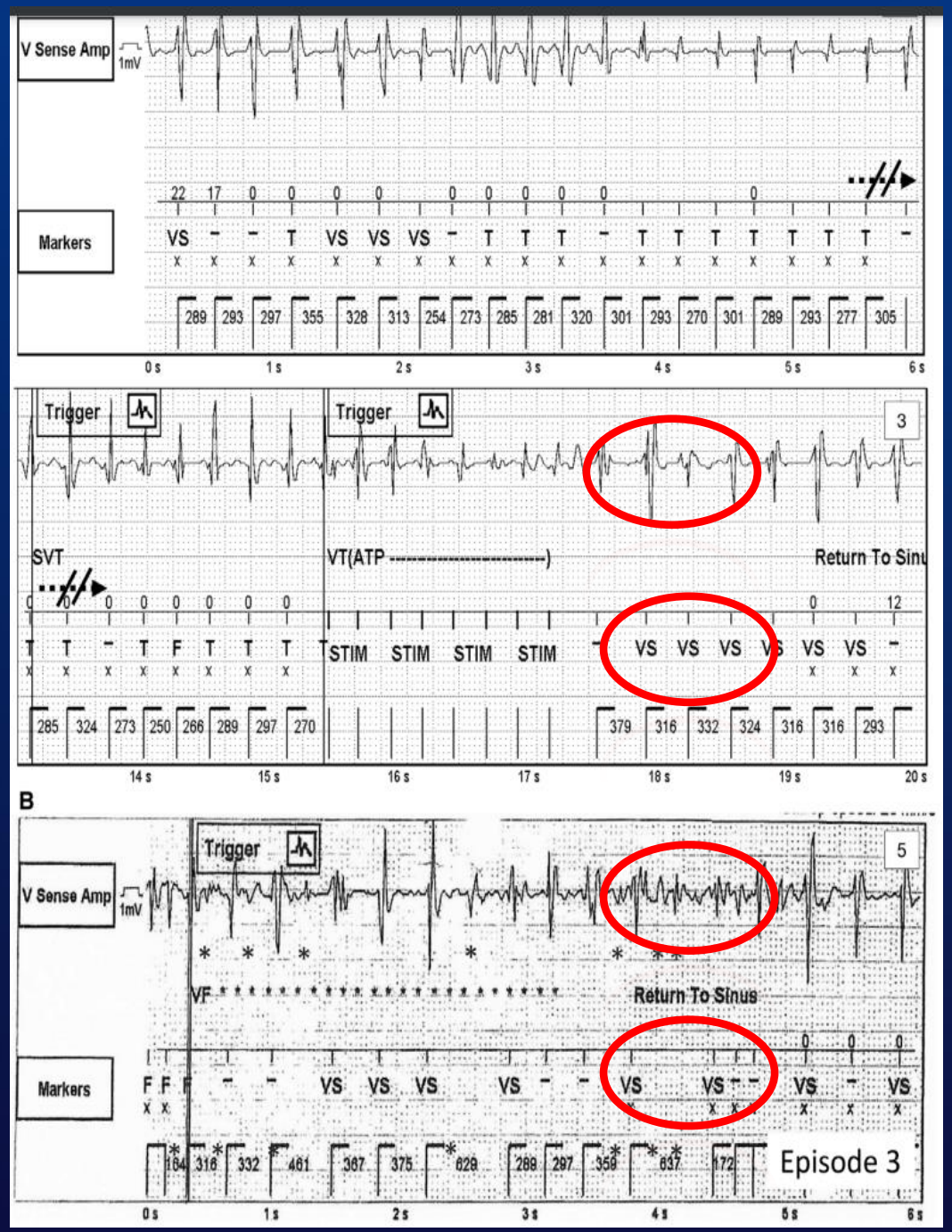
Long detection



Combination

- Straddle SR and VT

- Undersense



Differences

Parameter	Bipolar RV Channel	Discrimination Channel
Threshold Start	50%	**62.5%**
Decay Delay	60 ms	0 ms
Max Sensitivity	0,5 mV	0,3 mV
Sense ventr. refractory period	125 ms	**150 ms**
Ventricular Blanking	52 ms	52 ms (44 ms if AP < 2,5 V)
Slope	1 mV / 312 ms	1 mV / 312 ms
Low Frequency Attenuation	On	Off
Warm up	No	**Yes – 350 ms**
Programmable	Yes	**No**

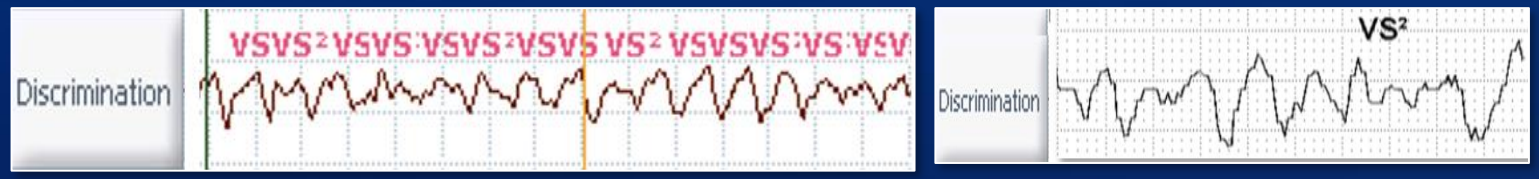
ASSURANCE for VF therapy !!

- VF Therapy Assurance uses the **DISCRIMINATION CHANNEL** to check for far-field under sensing during a potential ventricular episode (PVE)

- If it is determined that far-field **UNDERSENSING** is present, **VFTA IS TRIGGERED**

- Programmed parameters are **AUTOMATICALLY CHANGED** for the episode

VFTA Decision Criteria Summary



VFTA Checkpoints

1. Initial Detection or 45 Cycles after 1st binned event
2. Redetection
3. 15 cycles post-End of Episode

LOW AMPLITUDE COUNTER
2 consecutive signal amplitudes between 0.3 – 0.6 mV

NO

PAUSE COUNTER
2 seconds without a VS2 signal on Discrimination channel

NO

Normal Detection Protocol

YES

YES

Apply VFTA Detection Parameters

VFTA Decision Criteria

VFTA uses **TWO INDEPENDENT COUNTERS**

- Looks at Far Field signal only
- Measures Far Field signal **when VS2 marker is present**
- VFTA triggered when **EITHER ONE** is true

The **LOW AMPLITUDE COUNTER** helps identify signal dropout

- Sensing is present, but varying or very small
- Triggers VTFA if Low Amplitude Counter is ≥ 2

The **PAUSE COUNTER** looks every **two seconds** for pauses (potentially missed VF)

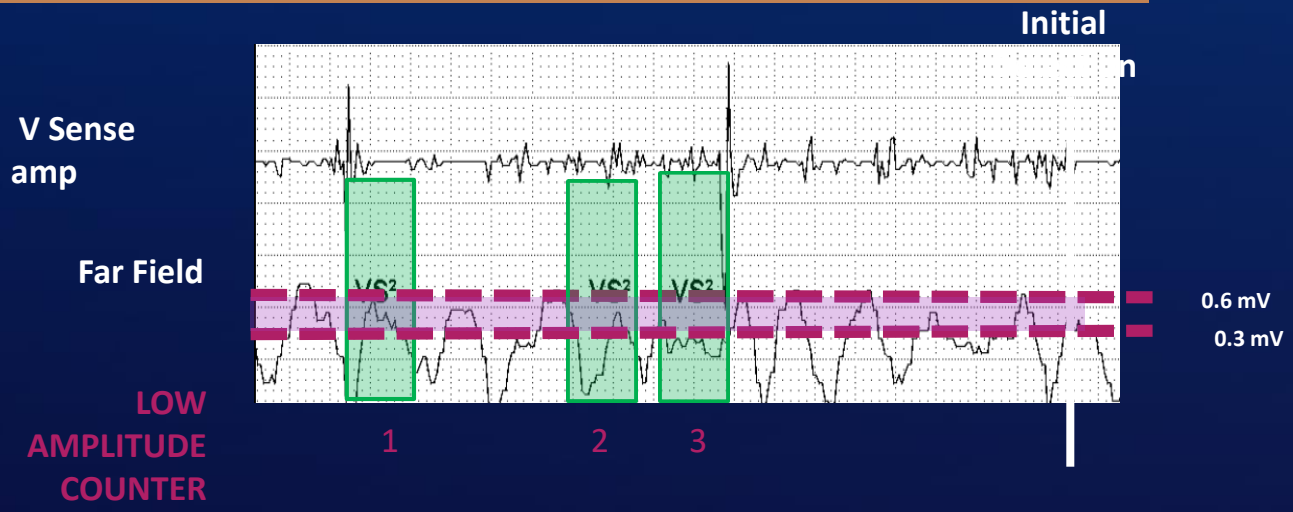
- Covers cases where sensing has been lost altogether on Far Field channel
- Triggers VFTA if Pause Counter is ≥ 1

VFTA Low Amplitude Counter Criteria

LOW AMPLITUDE COUNTER looks for **SIGNAL DROPOUT**
(sensing is present, but varying)

VTFA triggers if the Low Amplitude Counter is ≥ 2

- Small signals (0.3mV - 0.6mV) increment the counter by one.
- Large signals (> 0.6mV) reset the counter to zero.

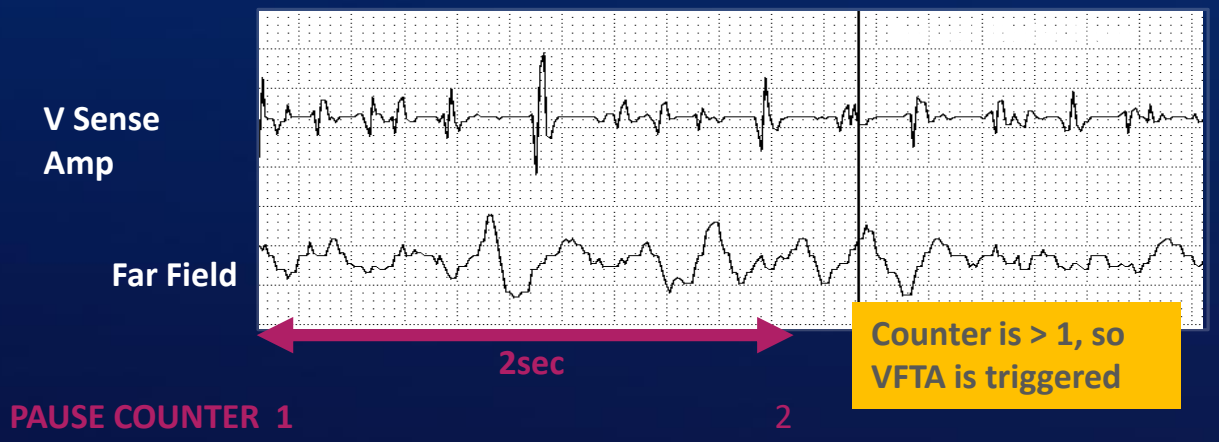


VFTA Pause Counter Criteria

The **PAUSE COUNTER** looks every 2 seconds for pauses

VFTA Triggers if the Pause Counter is ≥ 1

- Two Seconds without seeing a VS2 interval increments the VFTA counter by 1
- Large signals (> 1mV) with VS2 marker reset the counter

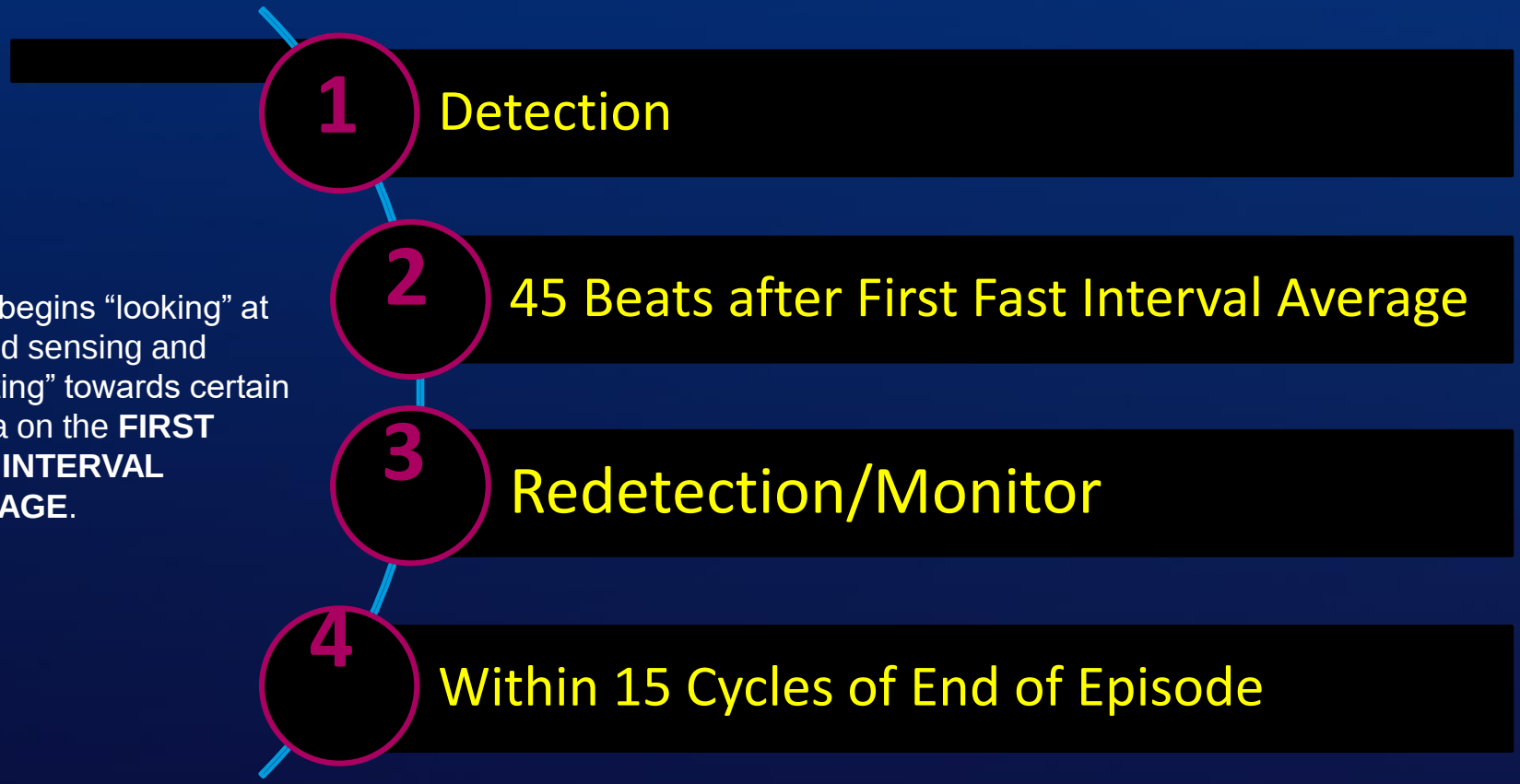


There are no VS2 markers; therefore, every 2 seconds the Pause counter increments by 1

VFTA CHECKPOINTS

WHEN DOES IT LOOK AT FAR-FIELD SENSING?

VFTA begins “looking” at far-field sensing and “counting” towards certain criteria on the **FIRST FAST INTERVAL AVERAGE**.



VFTA PARAMETER CHANGES

VFTA IS TRIGGERED – NOW WHAT?

1. Detection is changed to a **SINGLE THERAPY ZONE** – VF only

2. New “VF” detection rate is **DECREASED** to the **LOWEST PROGRAMMED ACTIVE THERAPY ZONE + 100 ms** (400 ms max)

   Note that if the lowest programmed active zone is slower than 150 bpm (400 ms), the device will drop below 150 bpm to the lowest programmed zone.

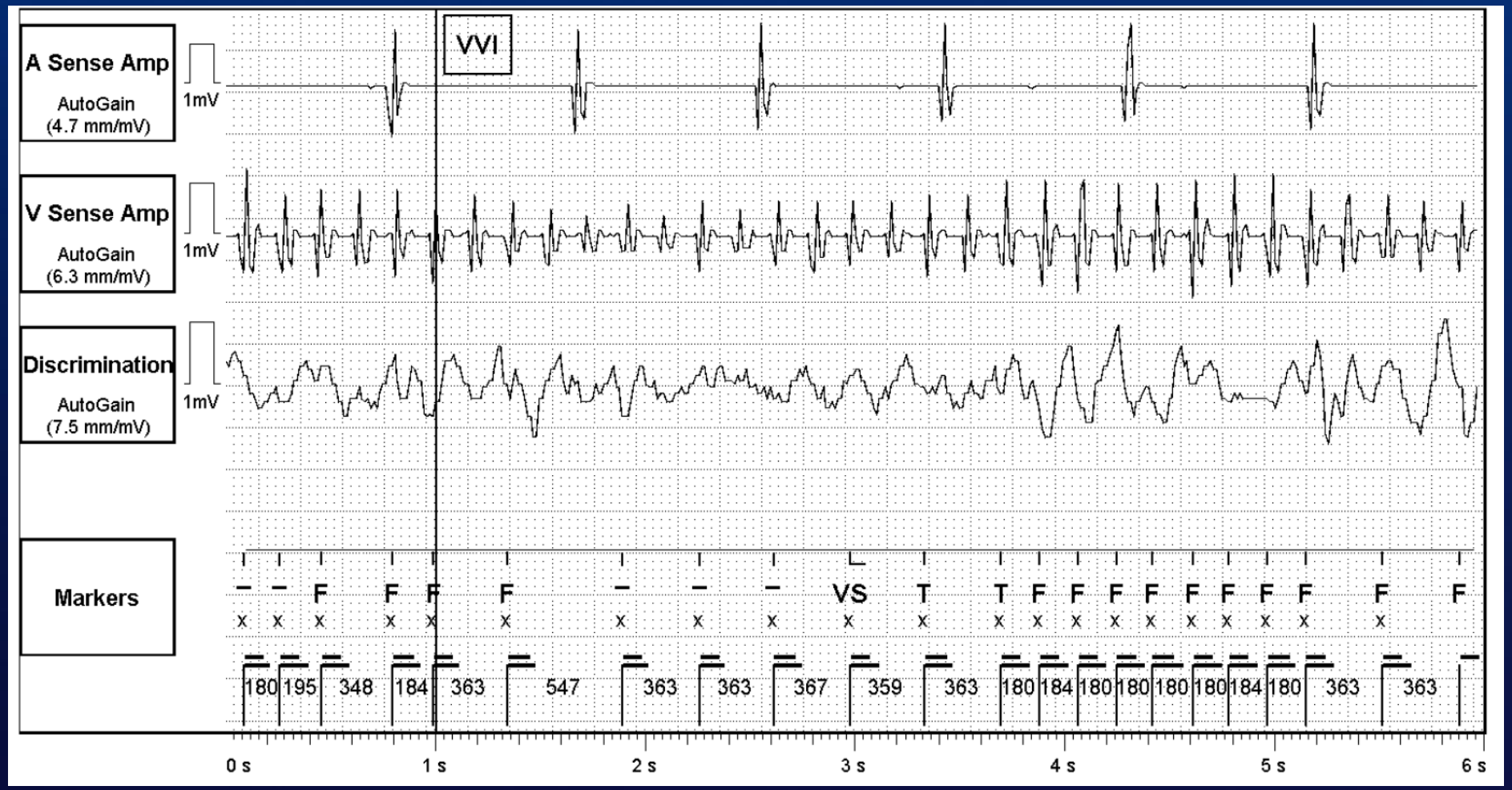
3. **NID** (number of intervals to detection) is **DECREASED TO 6**

4. **END OF EPISODE** (previously Return to Sinus) is increased to **7 INTERVALS**

5. Permanently programmed **VF ZONE THERAPIES** are used

VF Detection >280ms(214Bpm) VT 400 ms (150 Bpm)

Intermittent Undersensing not Meeting Detection Criterion



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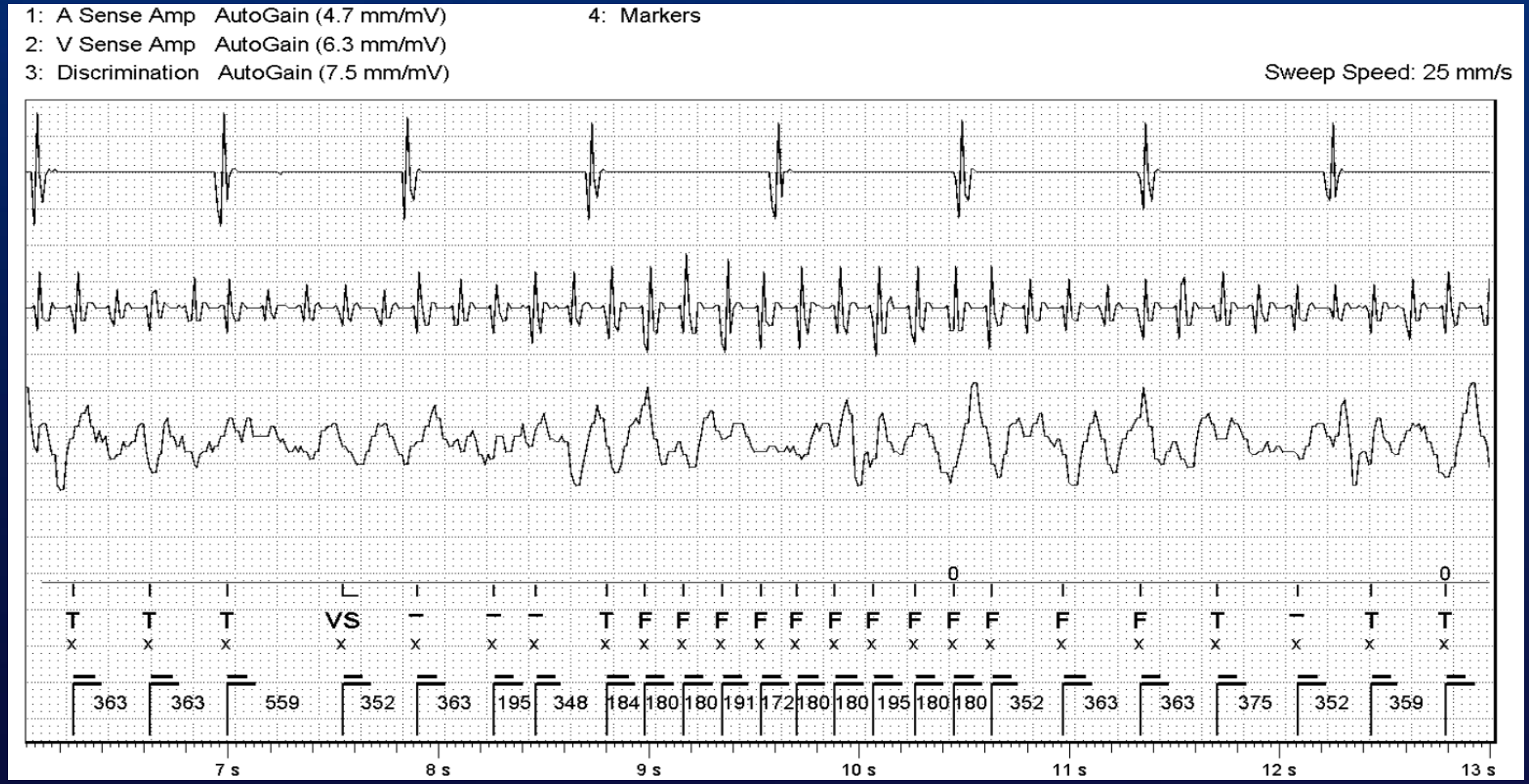
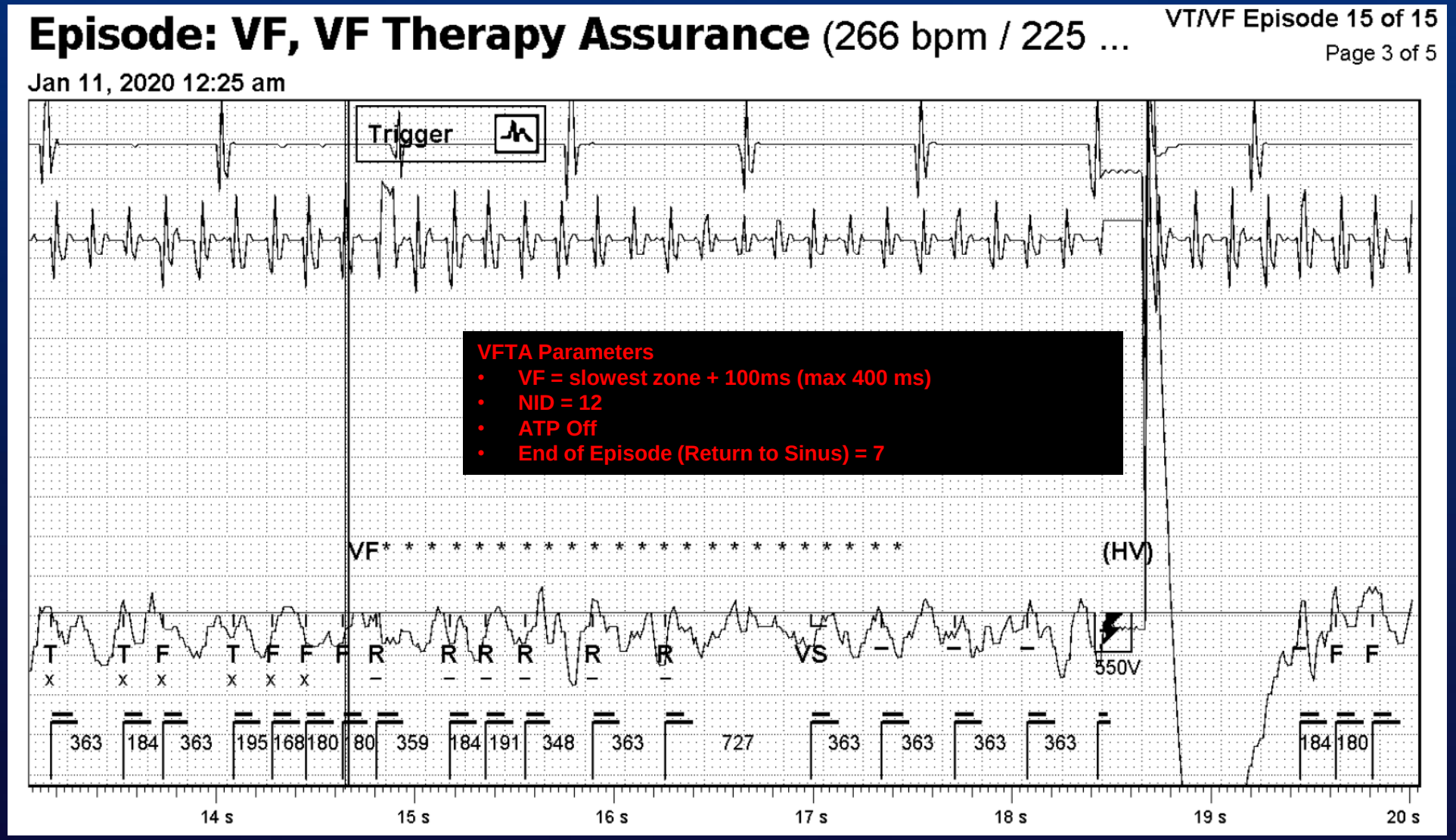
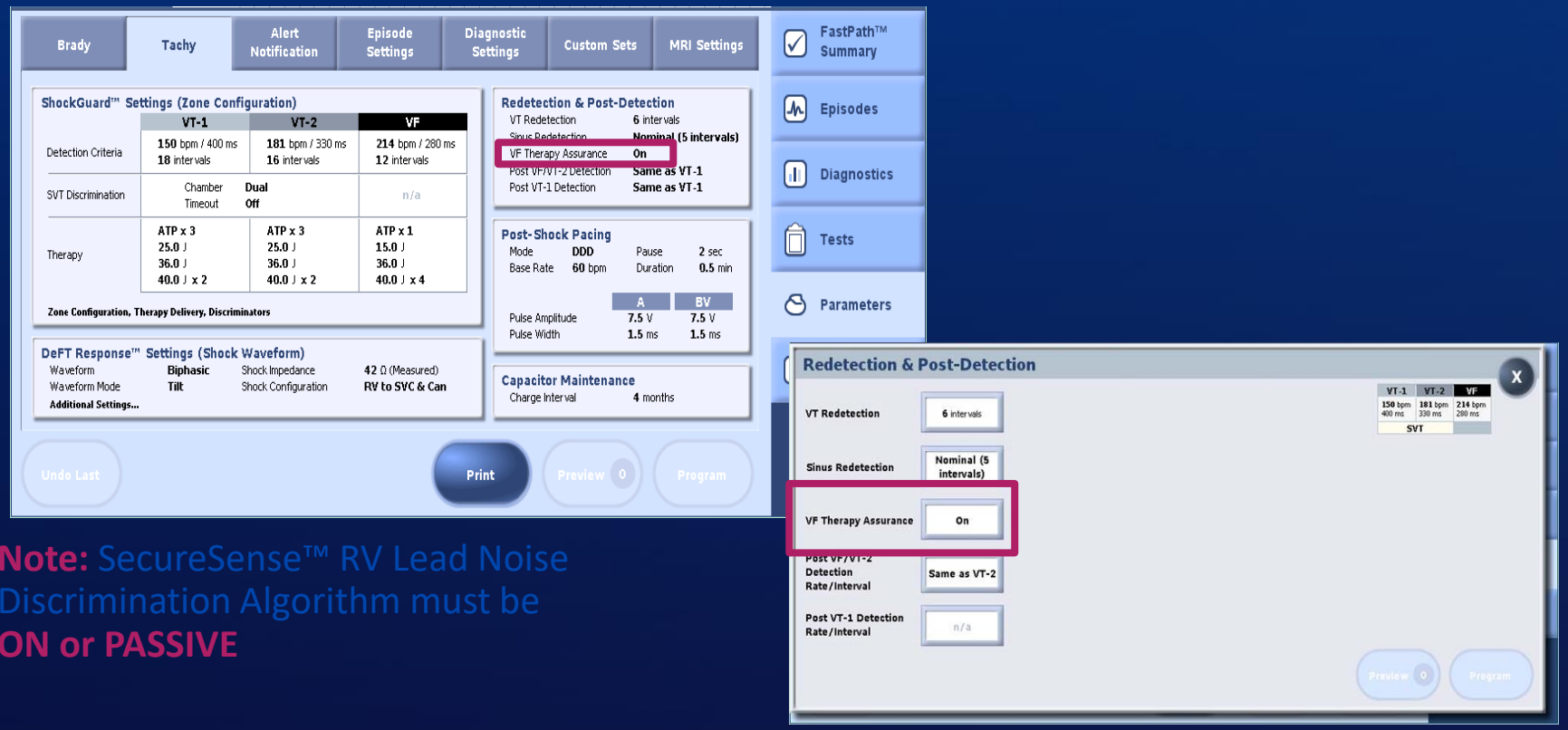


Same Patient



VFTA Triggered due to Low Amplitude on FAR Field Channel

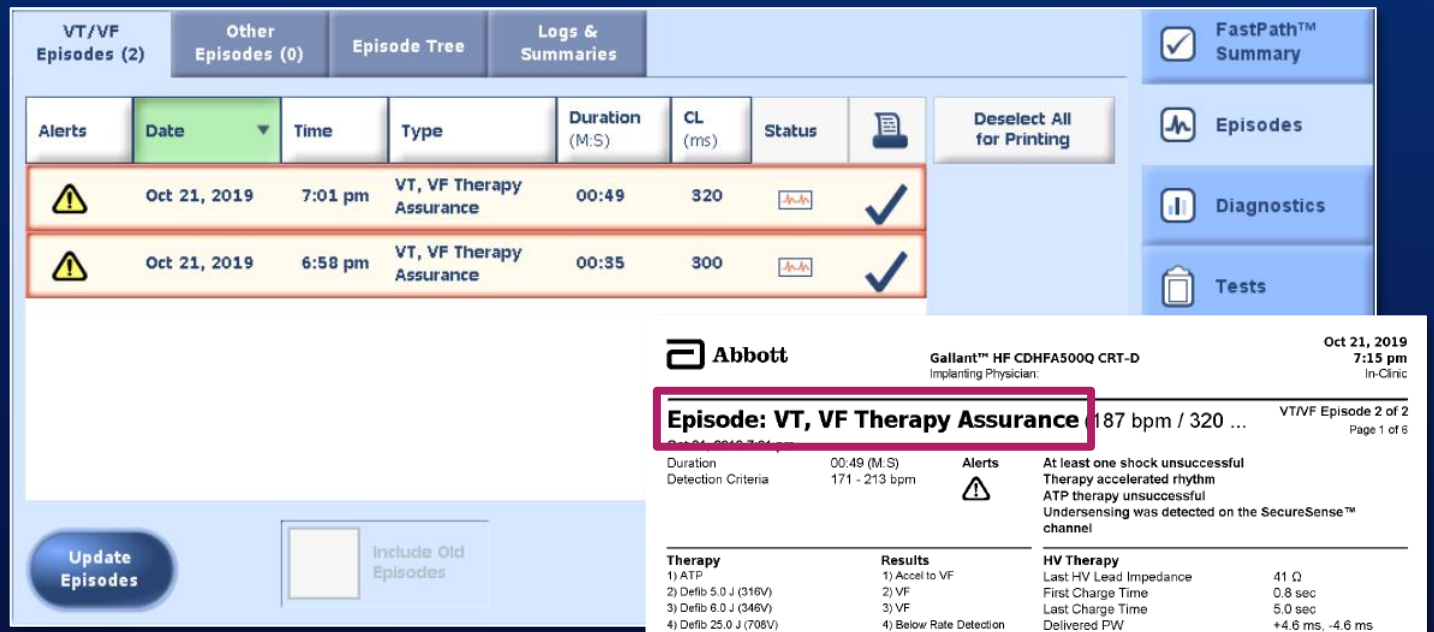
VFTA Simple Programming: ON* or OFF



Note: SecureSense™ RV Lead Noise Discrimination Algorithm must be **ON or PASSIVE**

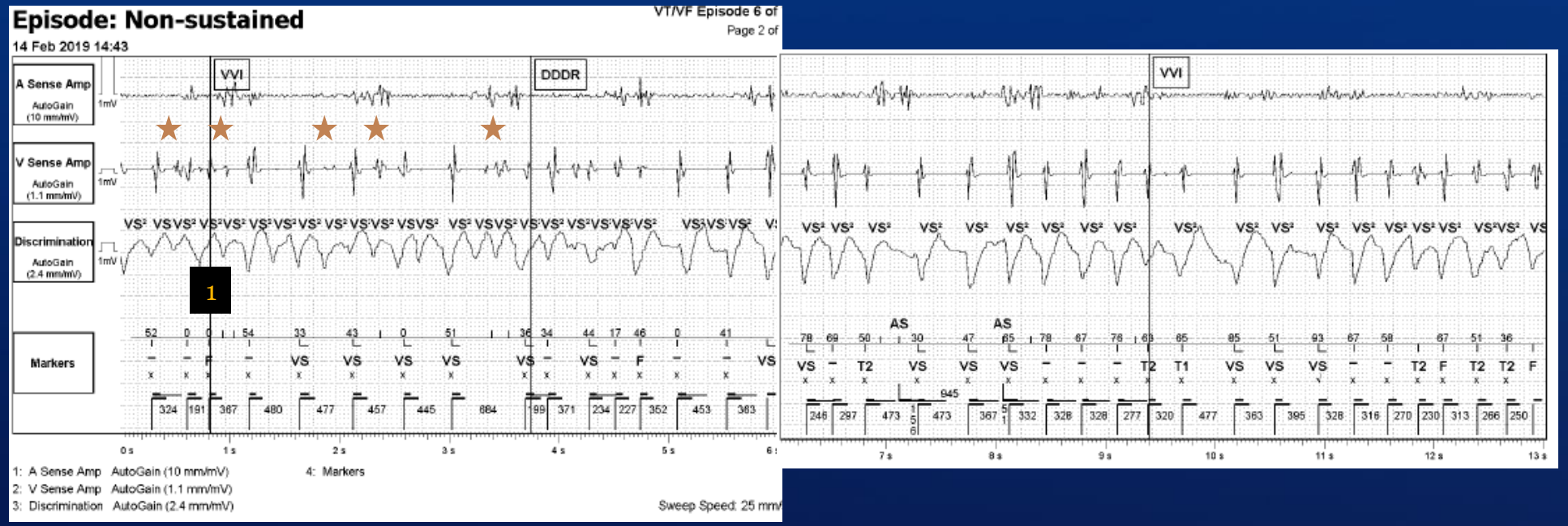
VFTA Diagnostics

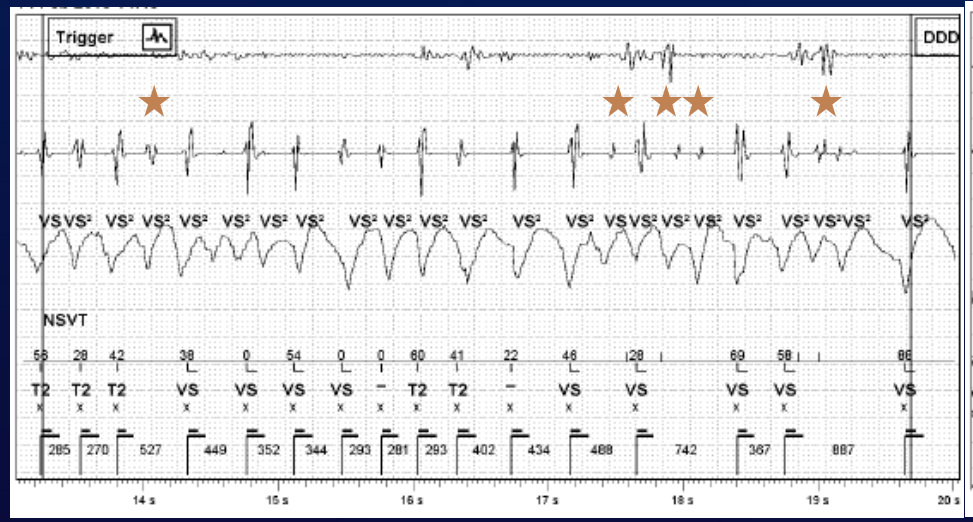
If VFTA is triggered, permanently programmed parameters should be assessed to see if permanent changes should be made

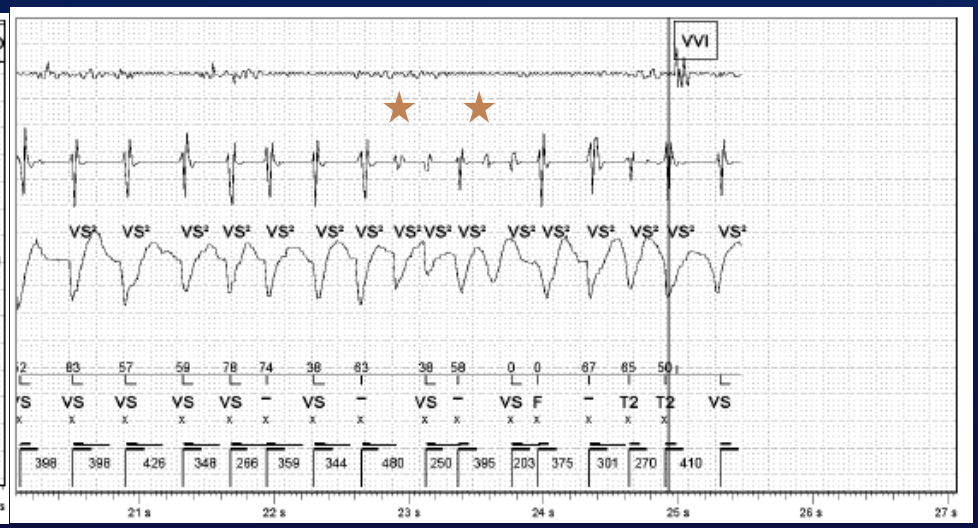


Polymorphic VT straddle detection zone: Near Field Undersensing with Good Far Field Sensing

(Long NID+ intermittent NF Undersensing)



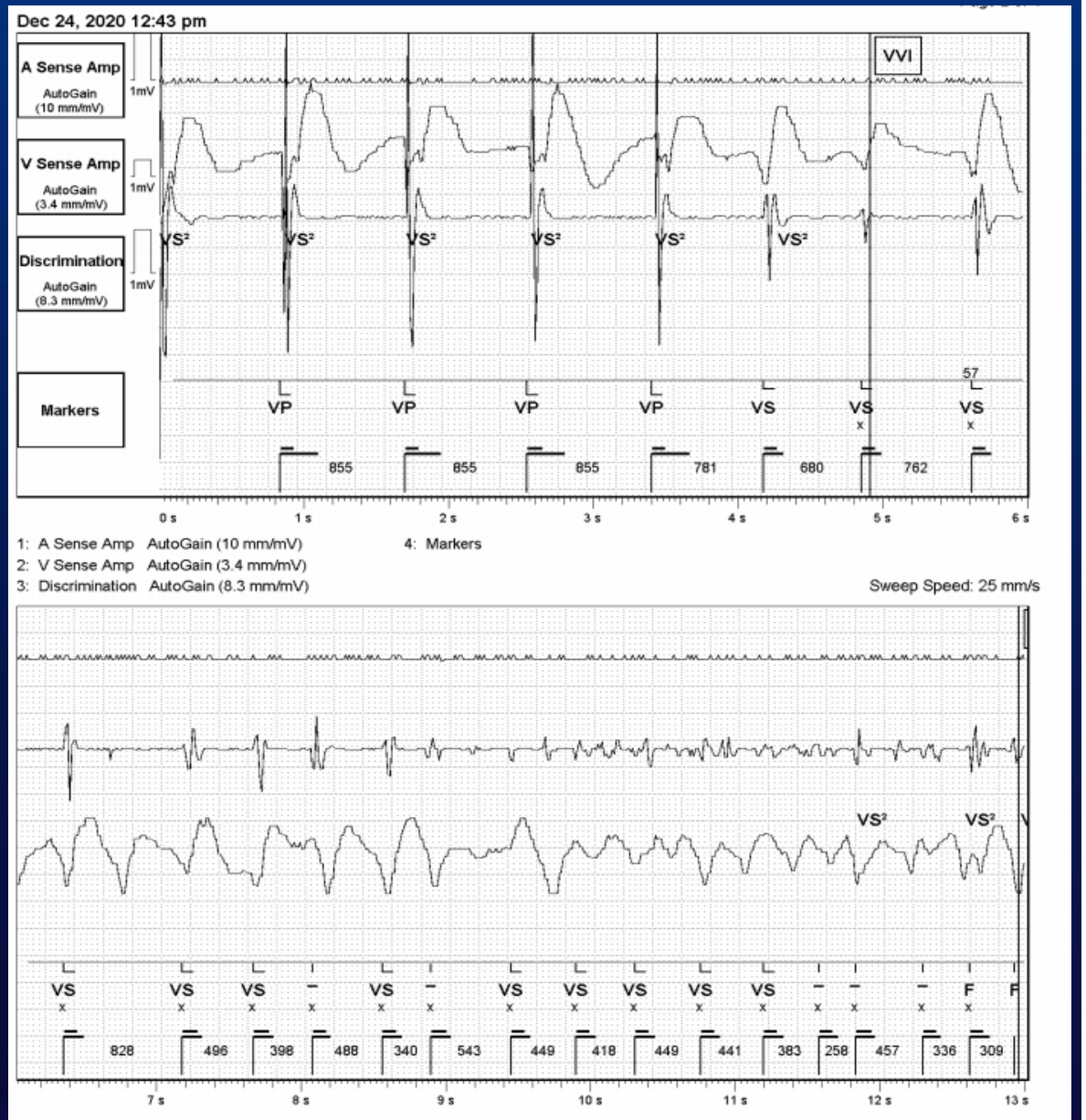


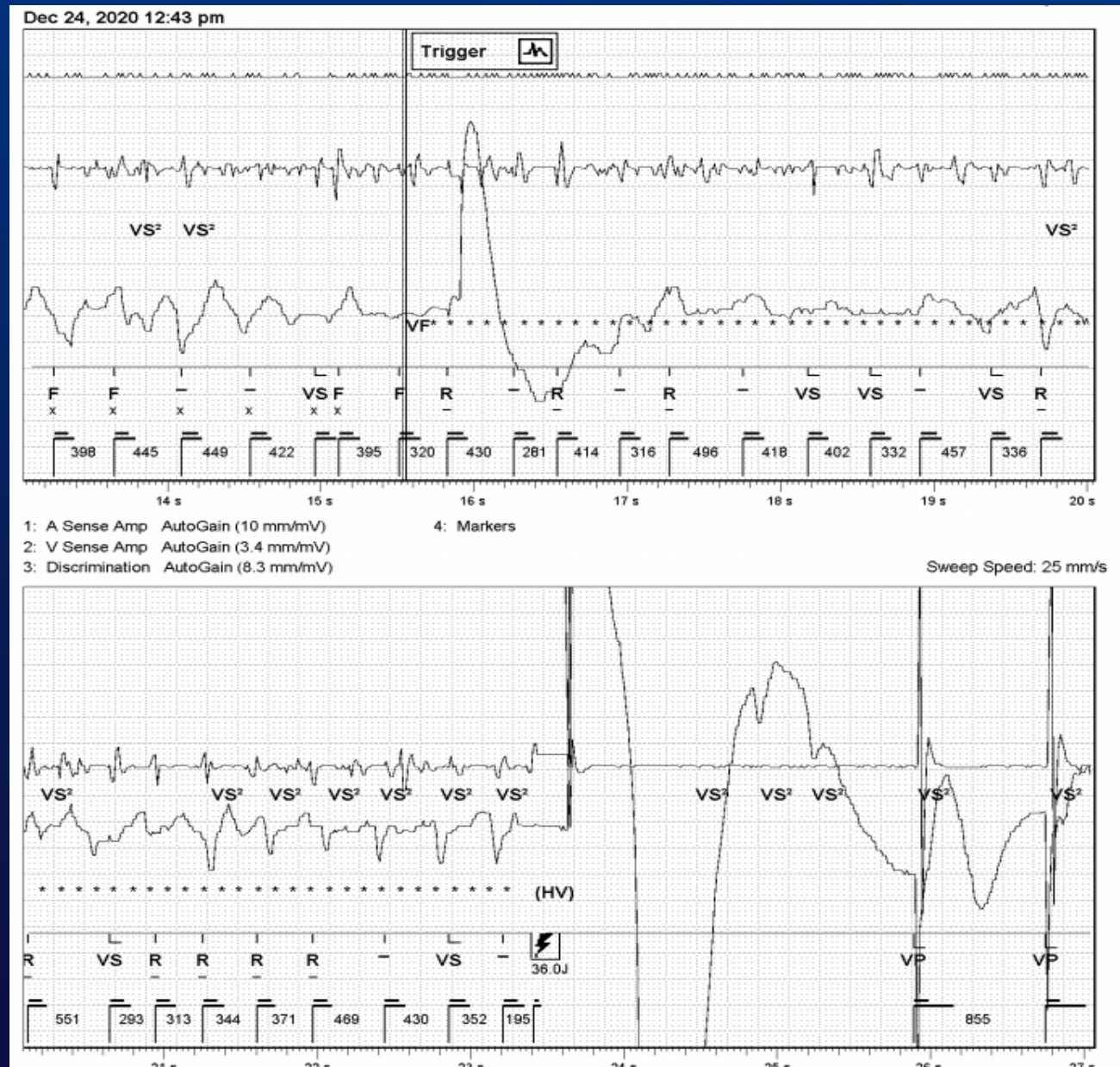


Premature Episode termination Due to NF Undersensing

Pause and Low Amplitude in FF often has clue

Another VFTA Episode





Results*

VFTA resulted in HV therapy for **86% of patients** who would have been **otherwise untreated** for potentially life-threatening arrhythmias.

Based on over 560,000 episodes (20,000 patients)

*Abbott Internal Validation Report 60101422.

Drawbacks of the VFTA

- No ATP
  - VF zone has no ATP
  - If in VT zone – is a drawback

- Needs to have VS2
- Needs to wait for a pause of 2s
- Charging depends on the capacitor status

Summary

- Shock avoidance is key with ICDs
- Long detection intervals has value towards this aim
- Under-detection due to under sensing can be counterproductive
- VFTA algorithm aims to address one of the shortcomings
  - VS2 counters; 2 s pause
  - Change in the detection settings for the given episode
- Shortcomings present

QUESTIONS

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