How to prevent inappropriate shock?

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Incidence of Inappropriate ICD Shocks

Clinical trial	Patient number	Follow-up (months)	Inappropriate Rx. (%)	Appropriate Rx. (%)	ATP yes/no	Outcome measure
AVID [12]	449	22	21	68 %	yes	n.a.
Pain Free II [8]	582	11	15	33	yes (50 %)	n.a.
MIRACLE ICD [13]	978	10	14 - 30 %*	23 % - 31 %**	yes	n.a.
MADIT-II [9]	719	20	12	21	Yes	mortality
SCD-HEFT [11]	811	46	17	23	No	mortality
ALTITUDE ICD [14]	39.396	28	16	23	Yes	mortality
ALTITUDE CRT-D [14]	29.904	28	17	23	Yes	mortality
Leiden [10]	1.544	41	18	n.a.	Yes	mortality

* 30 % in primary prevention patients, 14 % in secondary prevention patients

** 23 % in primary prevention patients, 31 % in secondary prevention patients

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Kutyifa V et al. Curr Cardiol Rep. 2014;16(6):496.

Inappropriate ICD Shocks in Yeungnam Province

Table 4. Rate of shock therapies and the clinical outcomes in the patients according to the indication for the device implantation

Total (n=146)	Primary prevention (n=36)	Secondary prevention (n=110)	p
Shock therapy			0.006
Yes	6 (16.7)	51 (46.4)	0.002
Appropriate shock	5 (13.9)	35 (31.8)	0.456
Inappropriate shock	1 (2.8)	16 (14.5)	
No	29 (80.6)	56 (50.9)	
ATP	1 (2.8)	3(2.7)	
Duration, first shock after device implantation (days)	422.33±351.16	302.17±450.81	0.533
Hospitalization	11 (30.6)	55 (50.0)	0.042
Death	10 (27.8)	26 (23.6)	0.617
Cause of death			0.763
Cardiac	6 (16.7)	17 (15.5)	
Non-cardiac	4 (11.1)	9 (8.2)	
Mode of death			0.491
Sudden	1 (2.8)	5 (4.5)	
Non-sudden	5 (13.9)	12 (10.9)	

Data are expressed as mean±standard deviation or number (%). ATP: anti-tachycardia pacing

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KH Park et al. Korean Circ J 2017;47:72-81

Causes of Inappropriate Shocks in MADIT II

Table 2 Rhythm Responsible for ICD Shock Episodes

Shock Type	Shock Episodes (n)	Percent
Appropriate	393	66.6
Inappropriate	184	31.2
Atrial fibrillation/flutter	81	13.7
SVT	67	11.4
Abnormal sensing	36	6.1
Unclassified	13	2.2
Total	590	100.0

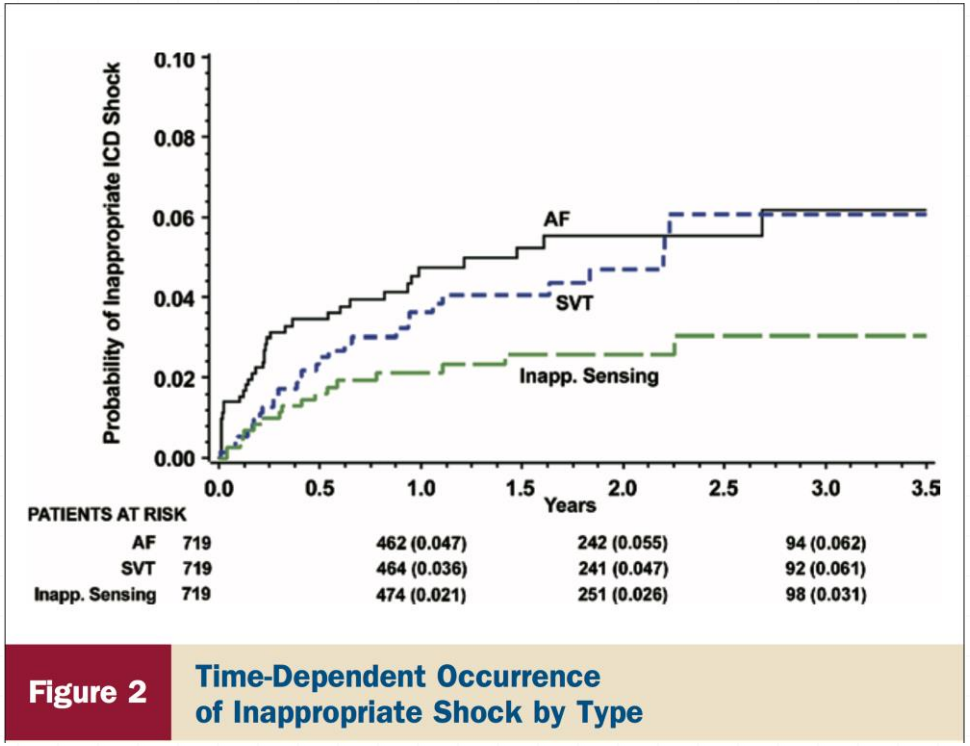

Figure 2 Time-Dependent Occurrence of Inappropriate Shock by Type

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Daubert JP et al. 2008;51:1357-65.

Prognosis after Shocks in HF patients

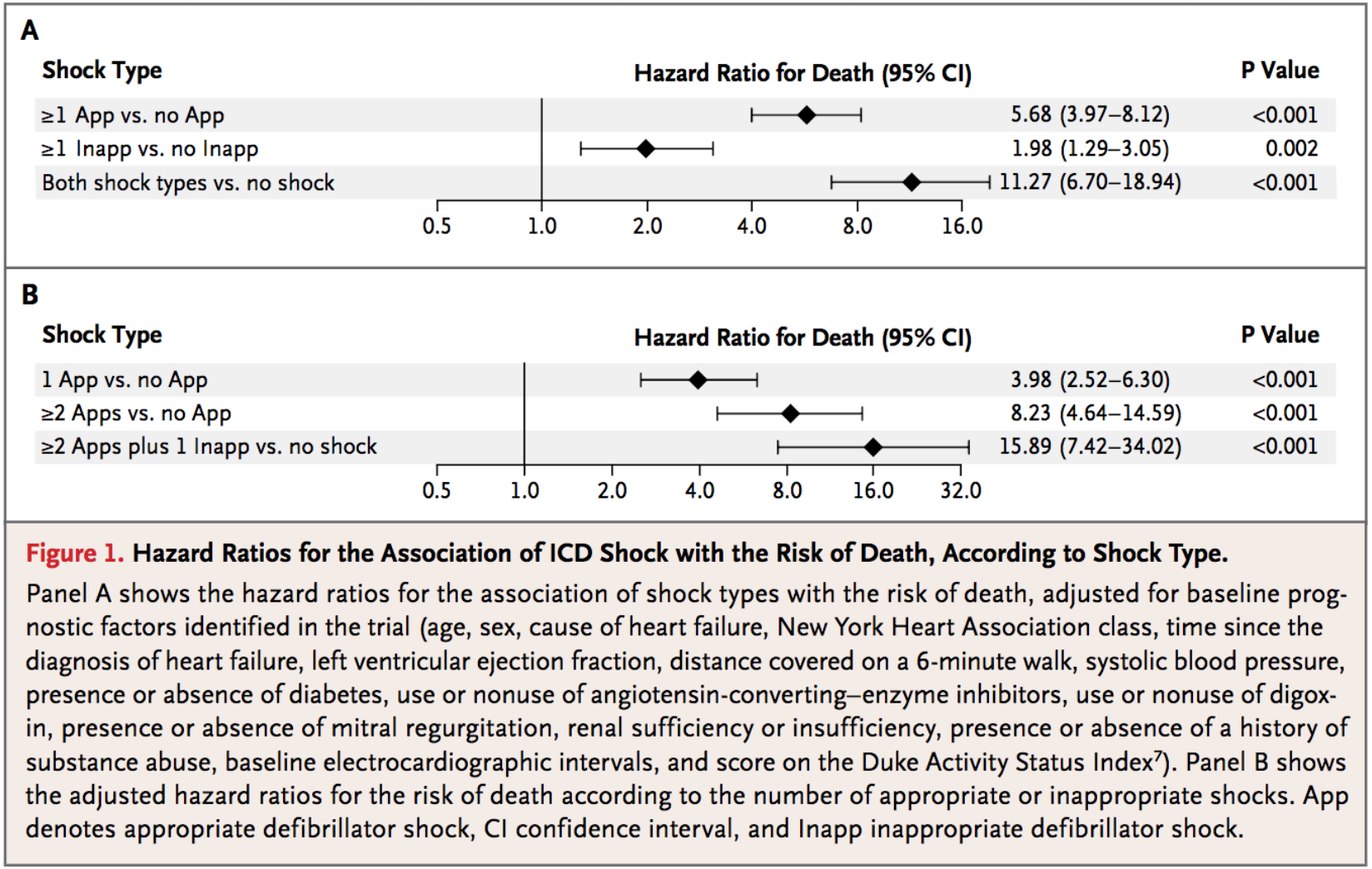

Figure 1. Hazard Ratios for the Association of ICD Shock with the Risk of Death, According to Shock Type.

Panel A shows the hazard ratios for the association of shock types with the risk of death, adjusted for baseline prognostic factors identified in the trial (age, sex, cause of heart failure, New York Heart Association class, time since the diagnosis of heart failure, left ventricular ejection fraction, distance covered on a 6-minute walk, systolic blood pressure, presence or absence of diabetes, use or nonuse of angiotensin-converting–enzyme inhibitors, use or nonuse of digoxin, presence or absence of mitral regurgitation, renal sufficiency or insufficiency, presence or absence of a history of substance abuse, baseline electrocardiographic intervals, and score on the Duke Activity Status Index[7]). Panel B shows the adjusted hazard ratios for the risk of death according to the number of appropriate or inappropriate shocks. App denotes appropriate defibrillator shock, CI confidence interval, and Inapp inappropriate defibrillator shock.

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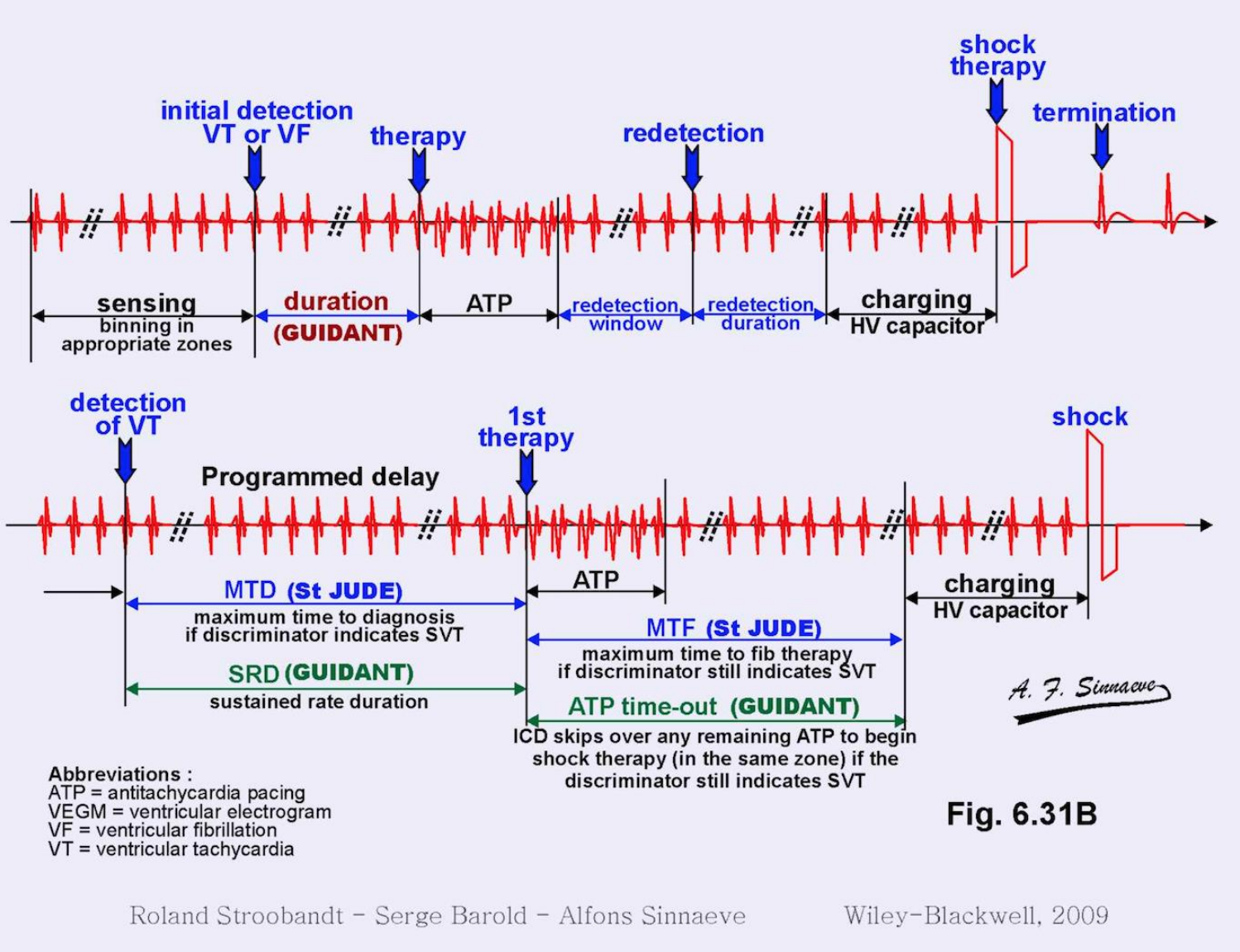
Poole JE et al. N Engl J Med. 2008 ;359:1009-17.

Summary of Sensing-Detection-Therapy



Roland Stroobandt – Serge Barold – Alfons Sinnaeve Wiley-Blackwell, 2009

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Reducing ICD Shocks : Evidence Based Programming

1. Detection rate
2. Detection duration
3. Antitachycardia pacing (ATP)
4. Algorithms that discriminate SVT from VT
5. Minimize the sensing of noise

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ICD Programming to Reduce ICD therapy

Clinical trial	Patient number	Follow-up (months)	Programming arms	Primary/ secondary	Syncope (HR, 95 % CI, p)	Mortality (HR, 95 % CI, p)	Inappropriate Rx. Reduction (HR, 95 % CI, p)	Appropriate Rx. Reduction (HR, 95 % CI, p)
EMPIRIC [33]	900	12	EMPIRIC: 150- 200 bpm VT 16 beats detection, 200-250 VT 18/24 beats, ATP shock, > 250 bpm shock, Tailored: physician custom settings	Primary/ secondary	No difference	No difference	0.95 (0.74 – 1.23), p=0.0016 Combined end point	
PREPARE [29]	700	12	PREPARE: ≥ 182 bpm 30 of 40 beats with discriminators and ATP, shock, Control: EMPIRIC + MIRACLE ICD patients	Primary	Morbidity index including syncope is reduced p=0.003	0.57 (0.29 – 1.11), p=0.10 adjusted	0.38 (0.16 – 0.86), p=0.02 adjusted	0.58 (0.30 – 1.12), p=0.11 adjusted
MADIT-RIT [34••] Arm B vs. Arm A	1.014	17	Arm A: conventional, VT zone ≥170 bpm, and VF zone ≥200 bpm Arm B: high-rate cut-off with therapy ≥200 bpm	Primary	1.32 (0.71 – 2.47), p=0.39	0.45 (0.24 – 0.85), p=0.01	0.21 (0.13 – 0.34), p<0.001	Arm B 9 % vs. A 22 %, p<0.001
MADIT-RIT [34••] Arm C vs. Arm A	1.000	17	Arm A: as above, Arm C: VT zone ≥170 bpm with 60 sec delay, ≥200 bpm with 12 sec delay, VF zone ≥250 bpm with 2.5 sec delay	Primary	1.09 (0.58 – 2.05), p=0.80	0.56 (0.30 – 1.02), p=0.06	0.24 (0.15 – 0.40), p<0.001	Arm C 6 % vs. A 22 %, p<0.001
ADVANCE-III [38]	1.903	12	30/40 interval vs. 18/24 interval detection	Primary/ secondary	No difference	No difference	0.63 (0.51 - 0.78), p<0.001 Combined end point	
PROVIDE [37, 39]	1600	12	Control: 3 zone, 150-180, 180-214, > 214 bpm 3. programming, 12 beats detection; Experimental: 2 zone, 180-214 bpm 25 beats detection, > 214 bpm 18 beats detection	Primary	Not published	Not published	Not published	Not published

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Kutyifa V et al. Curr Cardiol Rep. 2014;16(6):496.

PREPARE Study

Table 1 PREPARE VT/VF Programming Parameters

Detection		Threshold	Beats to Detect	Therapies
VF	On	250 beats/min	30 of 40	30 to 35 J (max output) × 6
FVT	via VF	182 beats/min	30 of 40	Burst (1 sequence), 30 to 35 J (max output) × 5
VT	Monitor	167 beats/min	32	Off

Table 4 ICD Detection and Therapy Programming

	PREPARE (n = 700)*	Combined Control (n = 689)
Treated rate threshold,† beats/min, median (25%, 75%)	182 (182, 182)	176 (162, 188)
VF number of intervals to detect, n (%)		
12 of 16	7 (1%)	397 (58%)
18 of 24	4 (<1%)	291 (42%)
24 of 32	0	1 (<1%)
30 of 40‡	687 (99%)	0
SVT discriminators ON, n (%)‡	690 (99%)	518 (75%)
Therapy		
At least 1 ATP attempt for ventricular rates, n (%)		
In VT zone§	1 (<1%)	203 (29%)
In FVT zone‡	693 (>99%)	171 (25%)
First VF therapy, J, n (%)		
<20	1 (<1%)	82 (12%)
20 to 29	10 (1%)	187 (27%)
30 to 35‡	687 (98%)	420 (61%)

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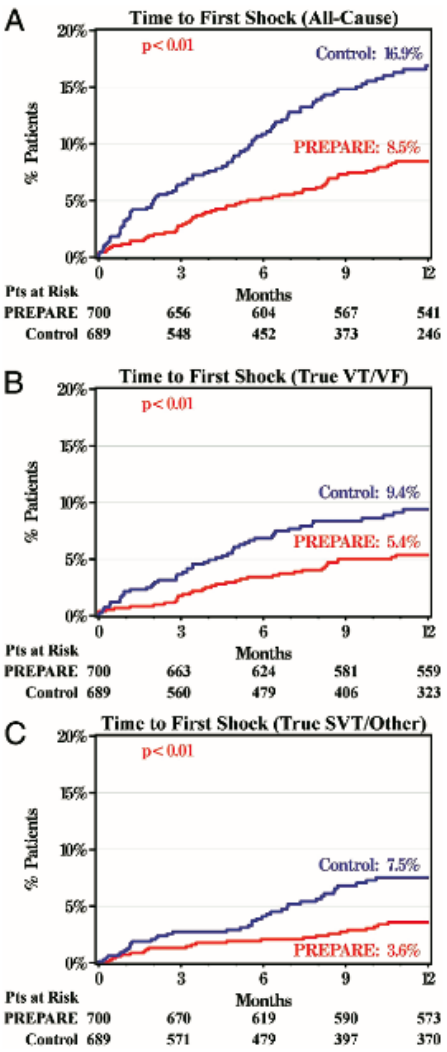
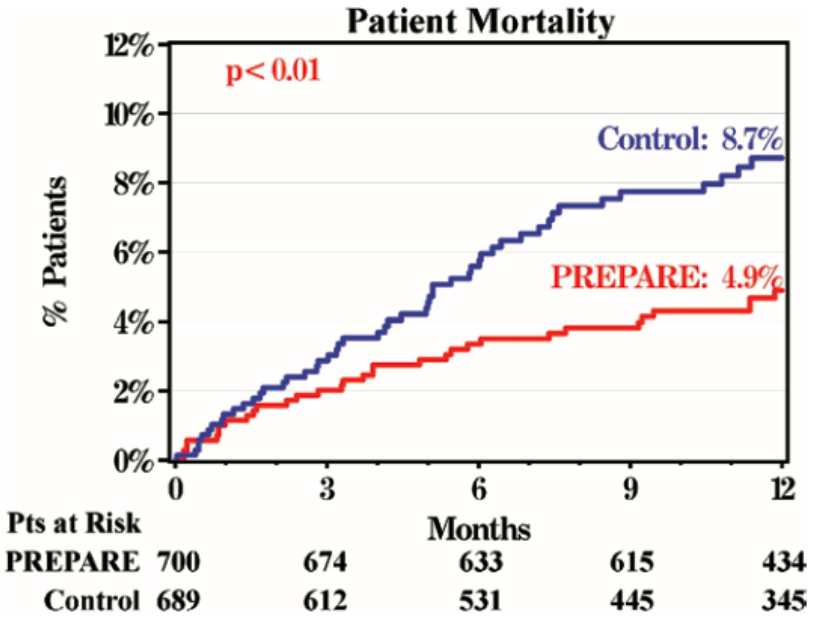
Wilkoff BL et al. J Am Coll Cardiol. 2008;52:541-50..

PREPARE Study





Wilkoff BL et al. J Am Coll Cardiol. 2008;52:541-50..

MADIT-RIT

Arm A (Conventional)	Arm B (High-rate)	Arm C (Duration-delay)
Zone 1:	Zone 1:	Zone 1:
≥170 bpm, 2.5s delay	170 bpm	≥170 bpm, 60s delay
Onset/Stability Detection Enhancements ON	Monitor only	Rhythm ID® Detection Enhancements ON
ATP + Shock		ATP + Shock
SRD 3 min initial		SRD Off
Zone 2:	Zone 2:	Zone 2:
≥200 bpm, 1s delay	≥200 bpm, 2.5s delay	≥200 bpm, 12s delay
Quick Convert™ ATP Shock	Quick Convert™ ATP Shock	Rhythm ID® Detection Enhancements ON ATP + Shock
		SRD Off
		Zone 3 :
		≥250 bpm, 2.5s delay
		Quick Convert™ ATP + Shock

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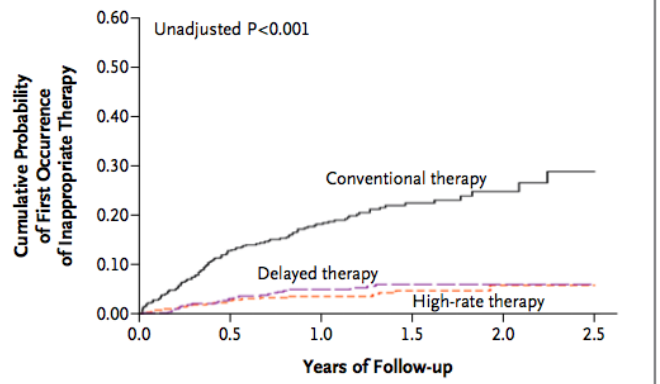
Moss AJ et al. N Engl J Med. 2012;367:2275-83.

MADIT-RIT

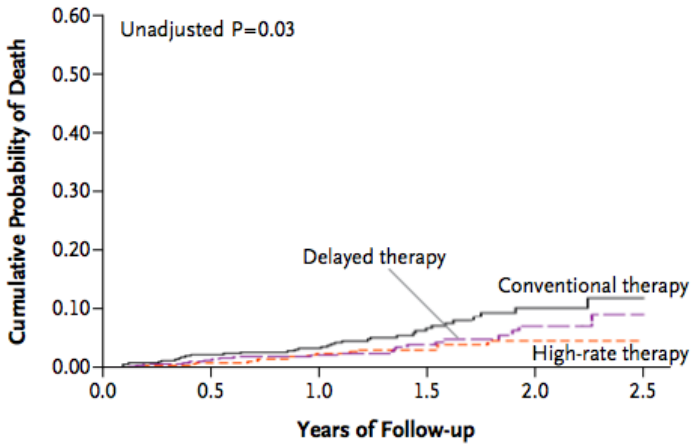


No. at Risk

Conventional therapy	514	420 (0.13)	305 (0.18)	149 (0.22)	56 (0.25)	8 (0.29)
High-rate therapy	500	454 (0.03)	339 (0.04)	191 (0.05)	70 (0.06)	17 (0.06)
Delayed therapy	486	445 (0.03)	342 (0.05)	177 (0.06)	82 (0.06)	13 (0.06)

Figure 1. Cumulative Probability of First Occurrence of Inappropriate Therapy According to Treatment Group.

The values in parentheses are Kaplan–Meier estimates of the cumulative probability of a first occurrence of inappropriate device-delivered therapy in patients randomly assigned to therapy programmed for delivery at a heart rate of 170 beats per minute or higher (conventional therapy), at a heart rate of 200 beats per minute or higher (high-rate therapy), or at a heart rate of 170 beats per minute or higher with longer tachyarrhythmia monitoring (delayed therapy).



No. at Risk

Conventional therapy	514	490 (0.02)	392 (0.03)	219 (0.07)	89 (0.10)	14 (0.12)
High-rate therapy	500	478 (0.01)	372 (0.02)	221 (0.03)	90 (0.05)	21 (0.05)
Delayed therapy	486	471 (0.01)	375 (0.02)	205 (0.04)	99 (0.07)	14 (0.09)

Figure 2. Cumulative Probability of Death According to Treatment Group.

The values in parentheses are Kaplan–Meier estimates of the cumulative probability of death.

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Moss AJ et al. N Engl J Med. 2012;367:2275-83.

ADVANCE III

Figure 2. Treatment Effect Regarding the Primary End Point and Its Components

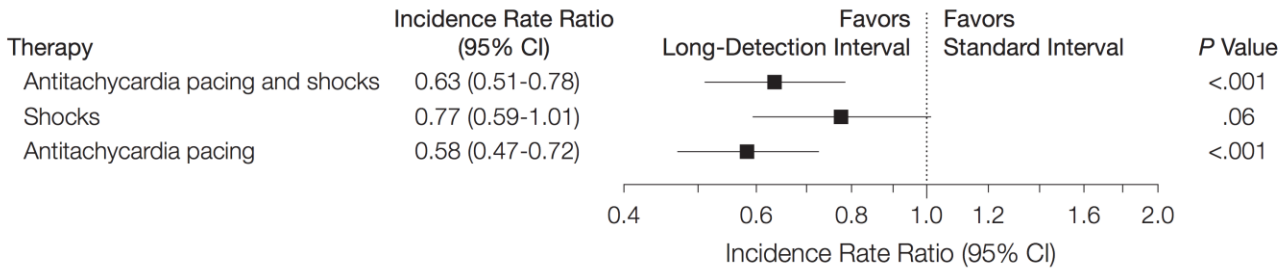
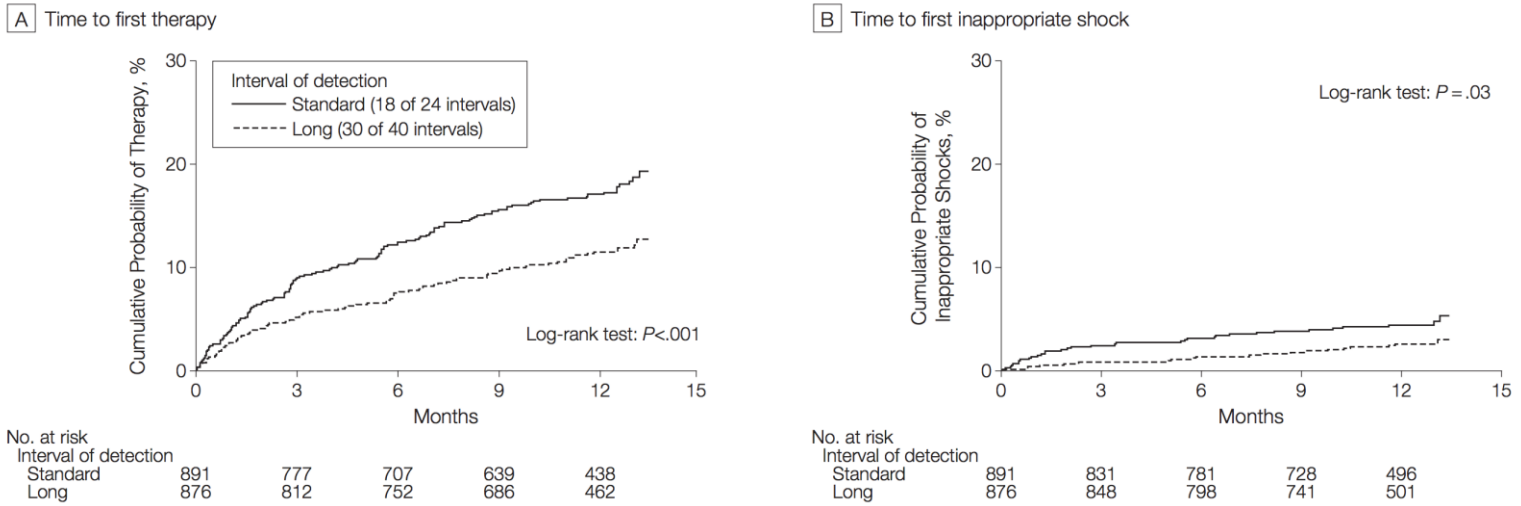


Figure 3. Kaplan-Meier Estimates of Time to the First Implantable Cardioverter-Defibrillator Therapy and to the First Inappropriate Shock in Each Group



Gasparini M et al. JAMA 2013;309:1903–1911.

ADVANCE III : in 2ndary Prevention

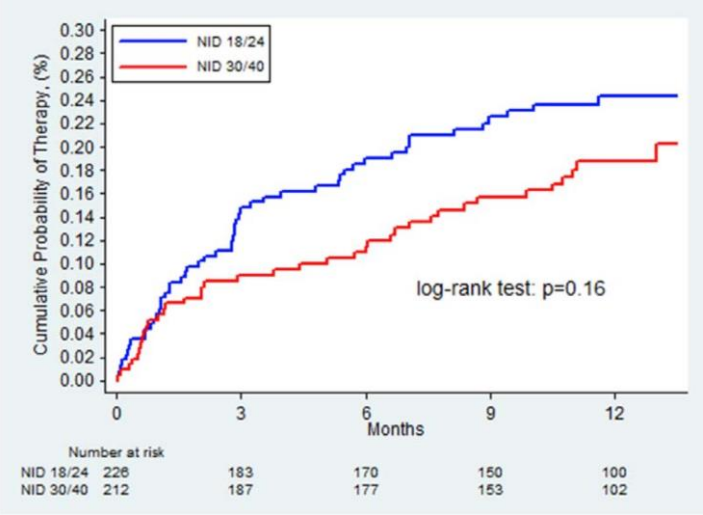


Table 3. Appropriate and Inappropriate Delivered Therapies as Separate End Points According to Intention-to-Treat Analysis

End Point	Detection Window NID	No. of Therapies (No. of Treated Episodes)	Therapy Rate per 100 Patient-Years	IRR (95% CI)	*P* Value
Appropriate delivered therapy					
Overall	18/24	191 (112)	89.7 (77.4–103.4)	1	0.029
	30/40	135 (80)	67.7 (56.8–80.2)	0.77 (0.60–0.97)	
ATP	18/24	112 (102)	52.6 (43.3–63.3)	1	0.37
	30/40	79 (71)	39.6 (31.4–49.4)	0.87 (0.64–1.18)	
Shock	18/24	79 (47)	37.1 (29.4–46.3)	1	0.018
	30/40	56 (50)	28.1 (21.2–36.5)	0.64 (0.45–0.93)	
Inappropriate delivered therapy					
Overall	18/24	53 (21)	24.9 (18.7–32.6)	1	0.014
	30/40	29 (9)	14.5 (9.7–20.9)	0.55 (0.34–0.89)	
ATP	18/24	24 (21)	11.3 (7.2–16.8)	1	0.050
	30/40	11 (9)	5.5 (2.8–9.9)	0.48 (0.23–1.00)	
Shock	18/24	29 (20)	13.6 (9.1–19.6)	1	0.15
	30/40	18 (6)	9.0 (5.4–14.3)	0.64 (0.35–1.18)	

ATP indicates antitachycardia pacing; CI, confidence interval; ICD, implantable cardioverter-defibrillator; IRR, incidence rate ratio; and NID, number of intervals to detect ventricular fibrillation.

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Kloppe A et al. Circulation 2014;130:308–314.

Tachycardia Detection Evidence

Study	Participants (N)	Short detection controls	Prolonged detection intervention	Findings
PREPARE	1391 Nonrandomized Primary prevention	12 of 16 (58%) 18 of 24 (42%)	30 of 40	Reduction in inappropriate shocks (SVT), avoidable shocks (VT), and "morbidity index"
RELEVANT	324 Nonrandomized Primary prevention	12 of 16	30 of 40	Reduction in inappropriate shocks (SVT), avoidable shocks (VT), and HF hospitalizations
MADIT-RIT	1500 Randomized Primary prevention	2.5 s (170–199 bpm) 1 s (≥200 bpm)	60 s (170–199 bpm) 12 s (200–249 bpm) 2.5 s (≥250 bpm)	Reduction in first inappropriate therapy, first appropriate therapy, appropriate ATP, and inappropriate ATP; improved survival
ADVANCE-III	1902 Randomized Primary & secondary prevention	18 of 24	30 of 40	Reduction in overall therapies, inappropriate shocks, and all-cause hospitalizations
PROVIDE	1670 Randomized Primary prevention	12 beats	25 beats (180–214 bpm) 18 beats (214–250 bpm) 12 beats (>250 bpm)	Reduction in all-cause shock rate; improved survival

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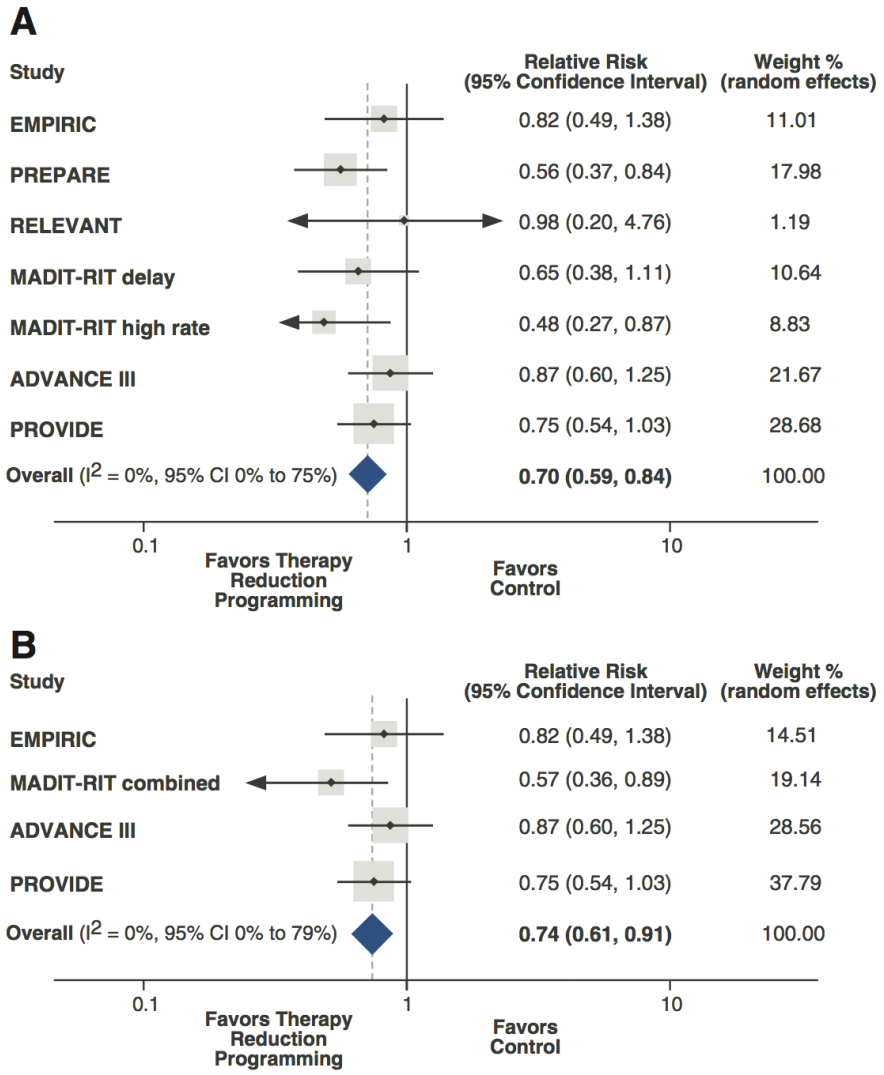
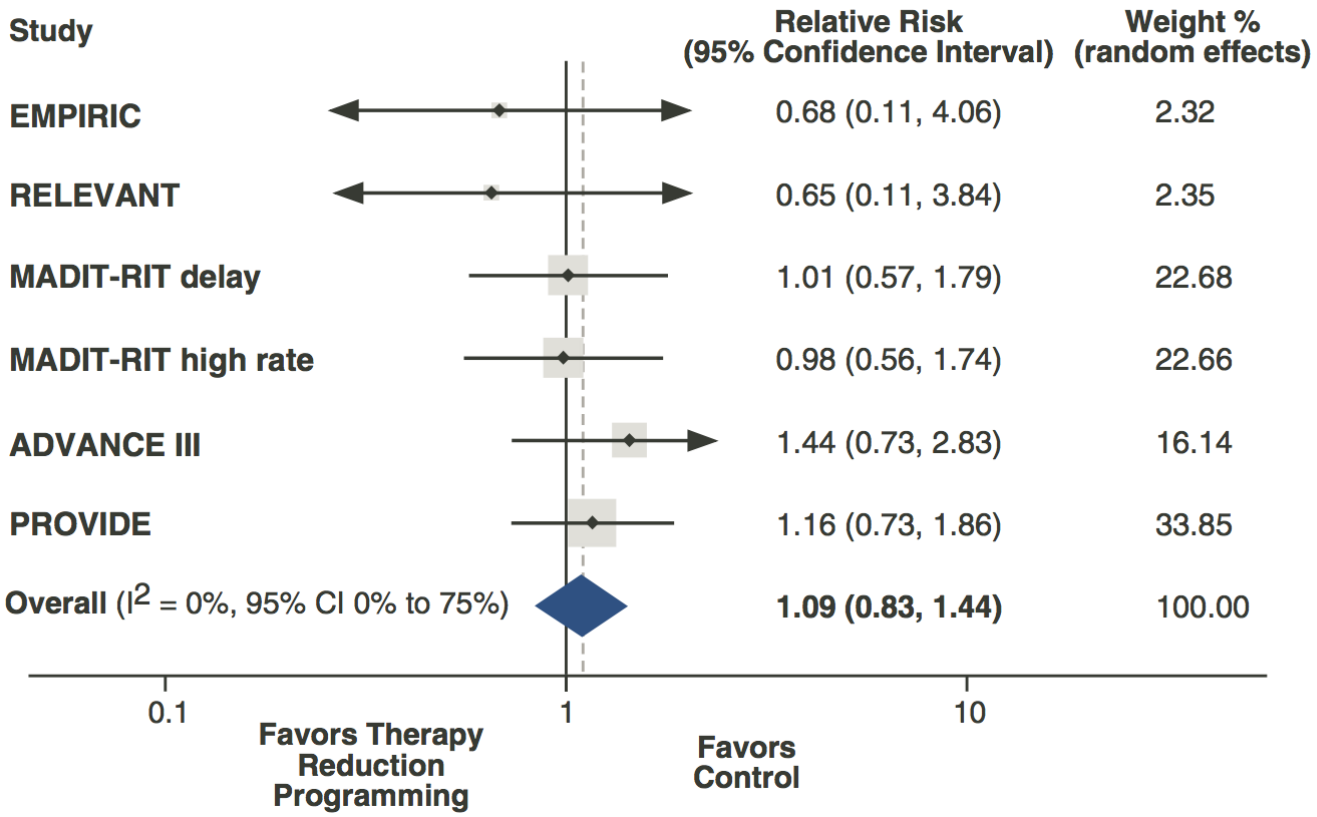
Wilkoff BL et al. Heart Rhythm. 2016;13:e50-86.

Meta-Analysis : All-cause mortality



Wilkoff BL et al. Heart Rhythm. 2016;13:e50-86.

Meta-Analysis : Risk of Syncope



Tann VH et al. Circ Arrhythm Electrophysiol. 2014;7:164-70.

ATP in Rapid VT : PainFREE RX II

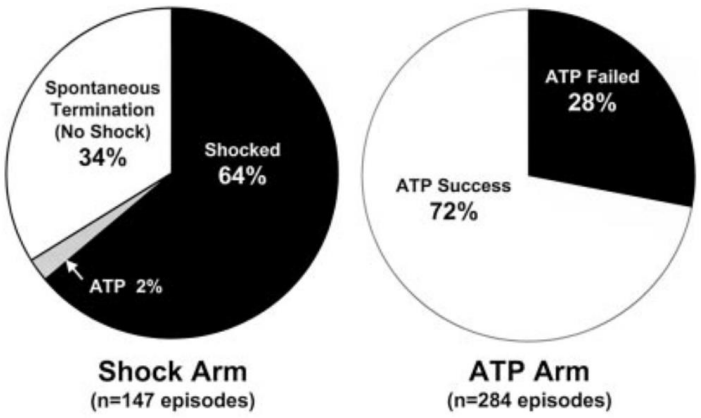


Figure 2. Terminating therapy for FVT episodes in each arm. Percentages are adjusted by generalized estimating equations.

TABLE 2. Outcomes Related to Patient Safety

Outcomes Related to Patient Safety	ATP Arm	Shock Arm
Acceleration (episodes), n (%)	4 (2)	2 (1)
Arrhythmic syncope (episodes), n (%)	2 (0.7)	1 (0.7)
Median episode duration, s	10.0	9.7
Mortality (patients), n (%)		
All	32 (10)	24 (7)
Sudden cardiac	1 (0.3)	2 (0.6)

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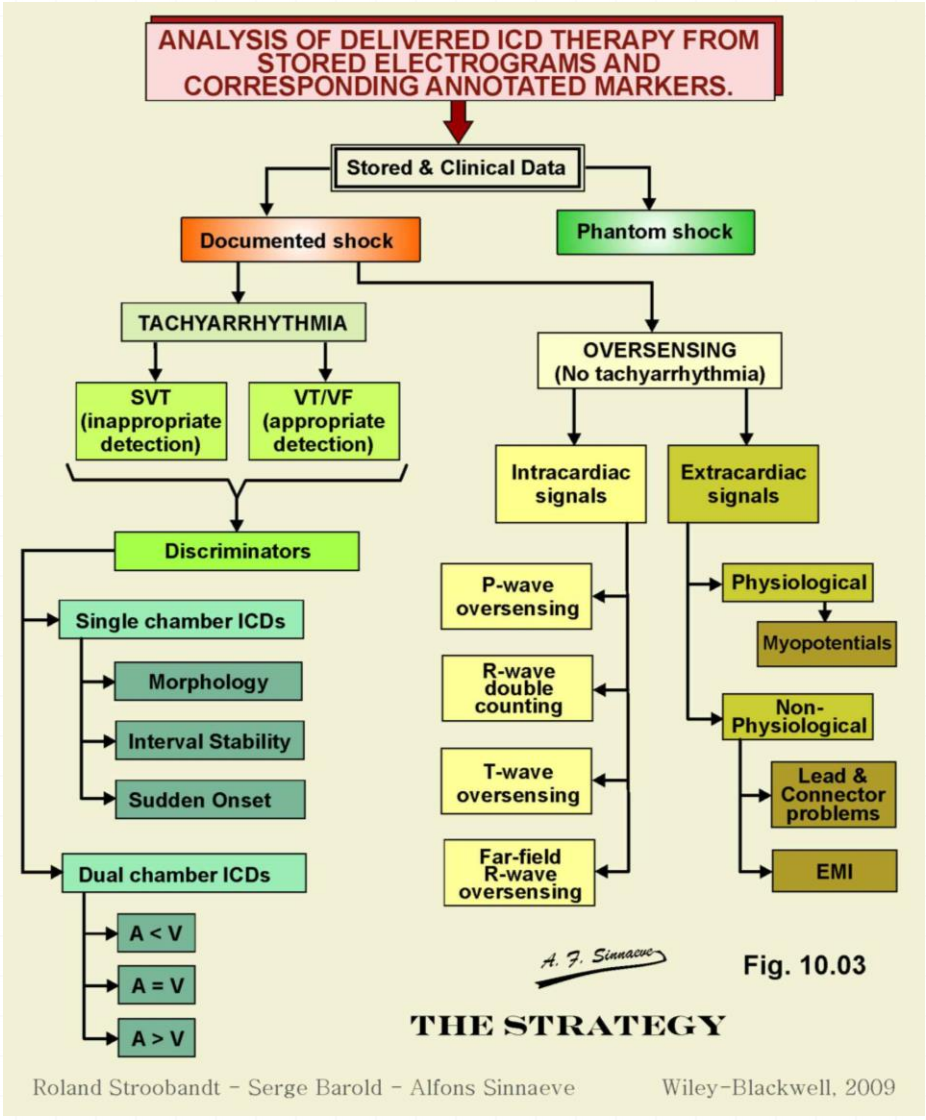
Wathen MS et al. Circulation. 2004;110:2591-6.

SVT-VT Discrimination



Stroobandt RX et al. ICD Step by Step – An illustrated Guide

Single Chamber Discriminators

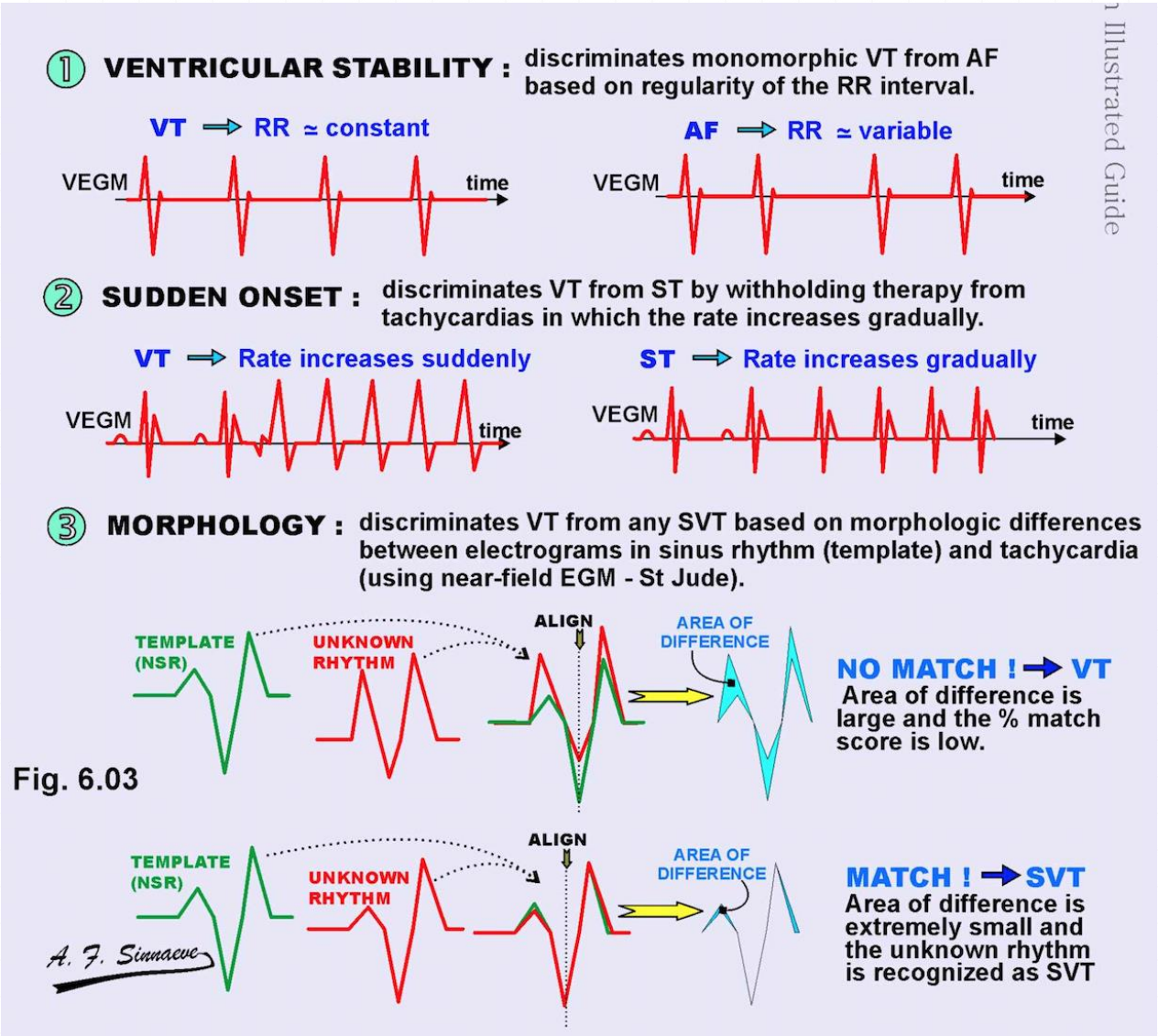


Fig. 6.03

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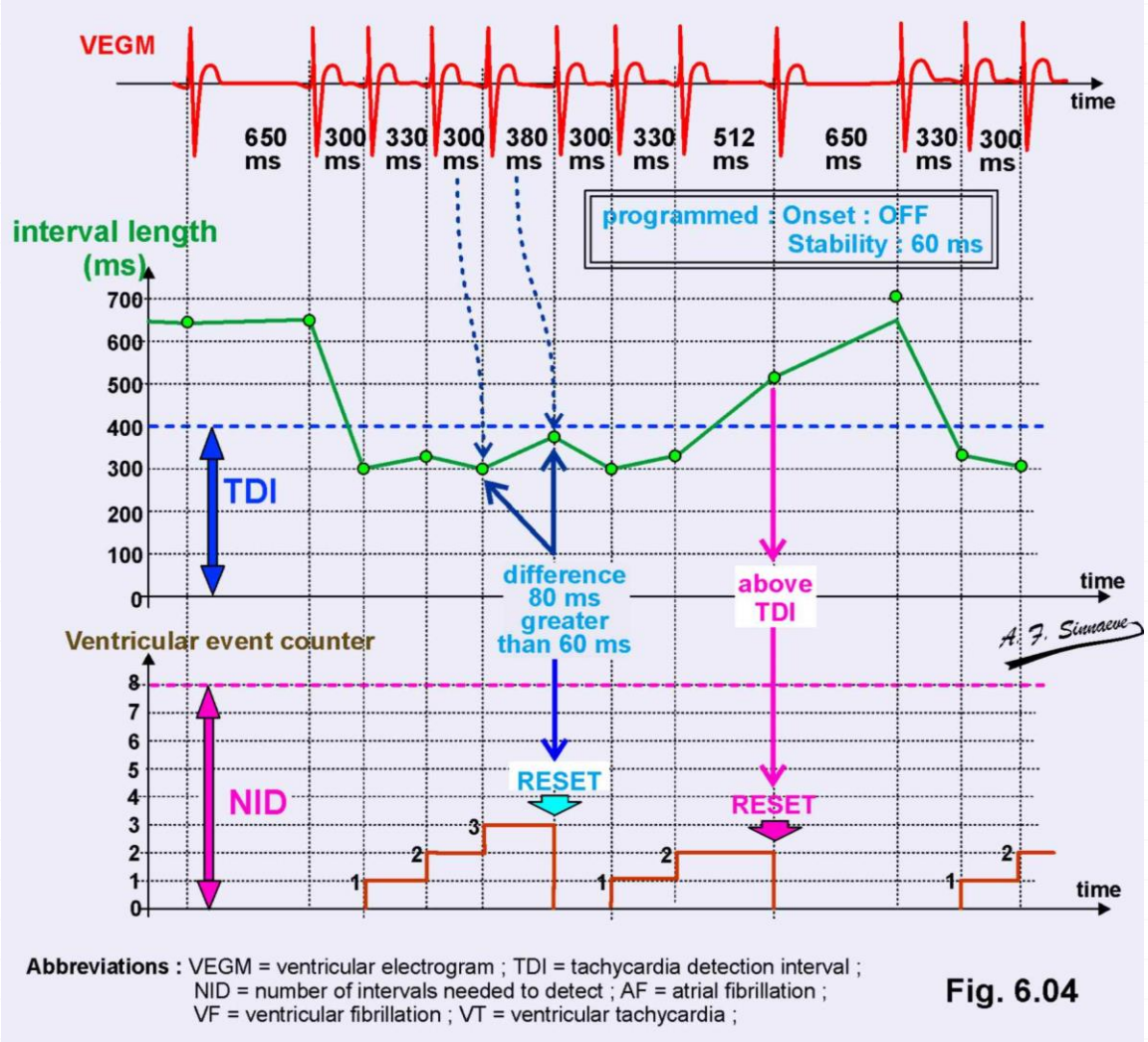
The Stability Criterion



The Sudden Onset Criterion

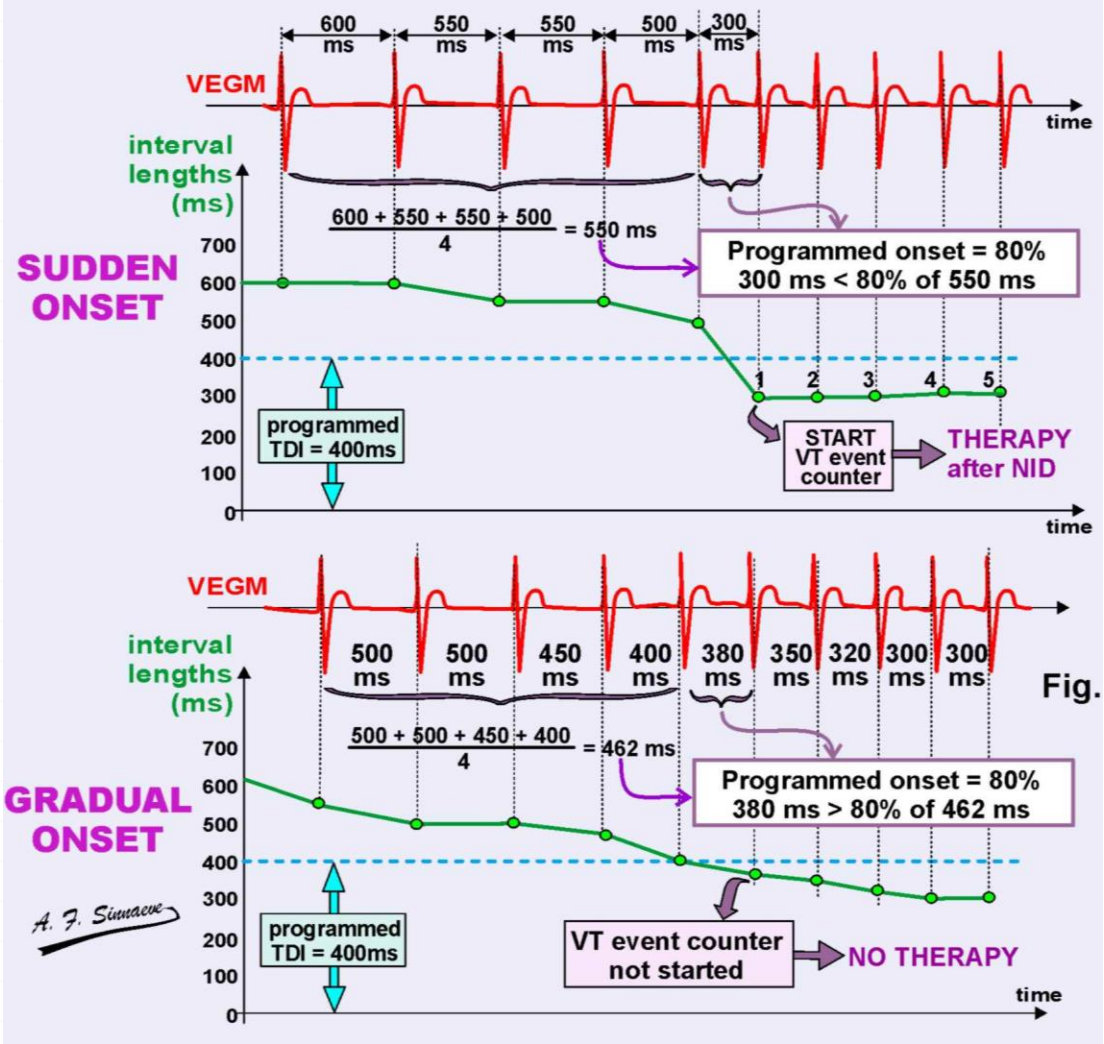


Fig.

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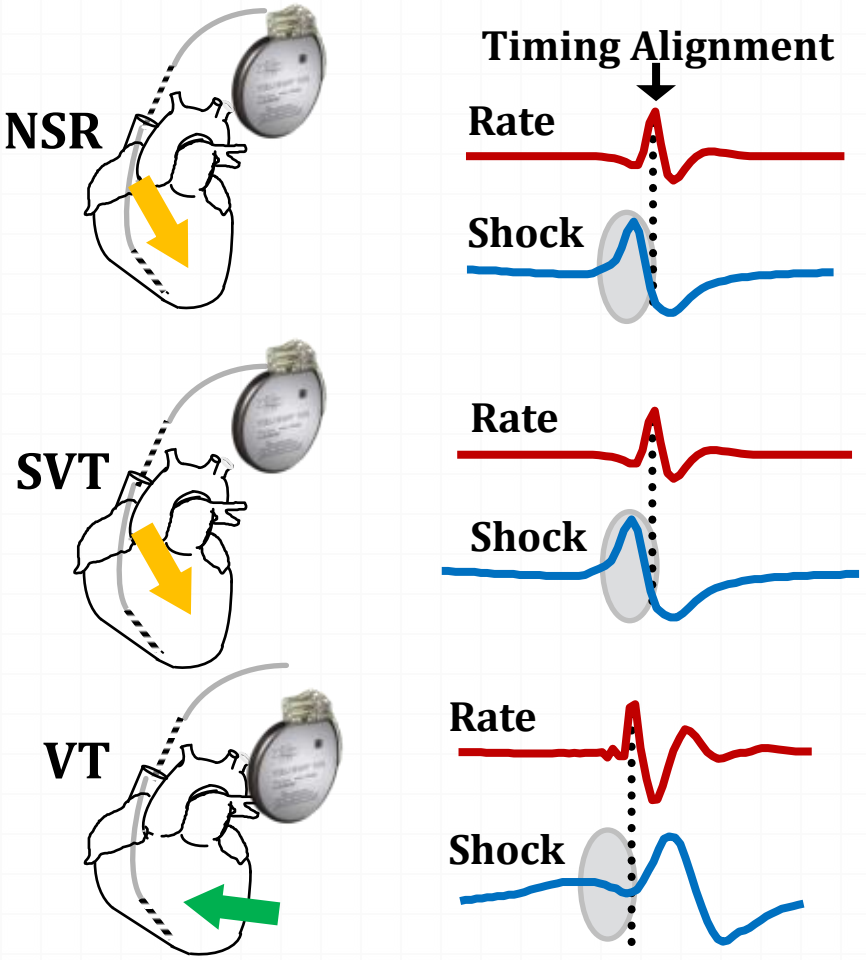
Rhythm ID™ Vector Timing & Correlation



NSR template is acquired and stored

SVT shock signal is very *similar* to NSR shock signal

VT shock signal is very *different* from NSR shock signal

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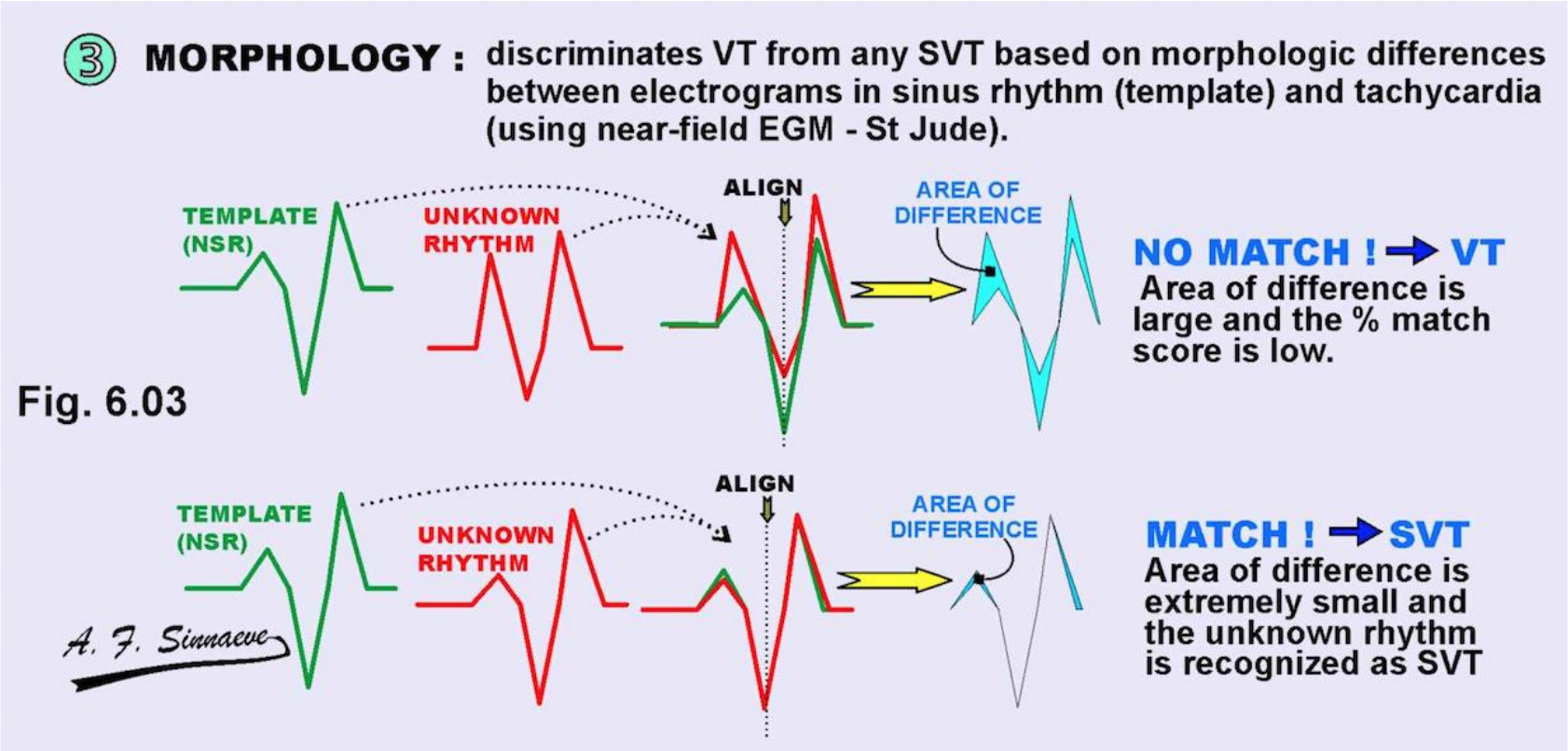
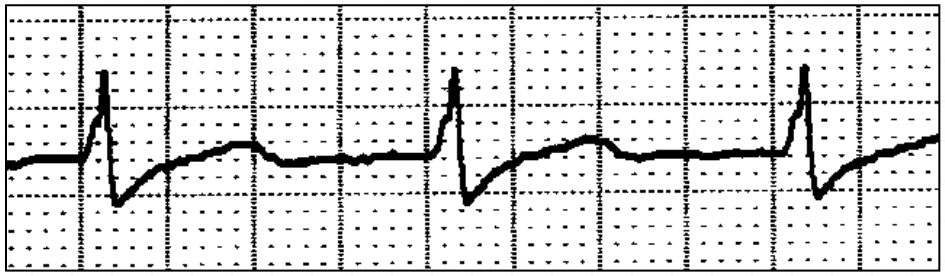
Compares the Surface Areas of the Peak



Wavelet Template Matching - Marquis VR

Intrinsic Normal Rhythm

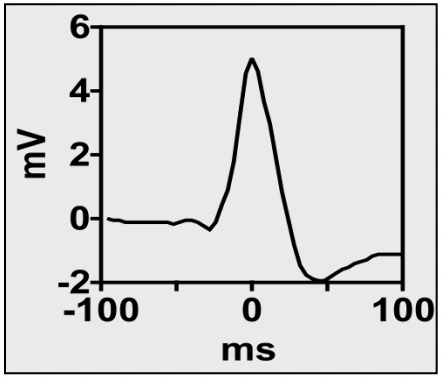


Create

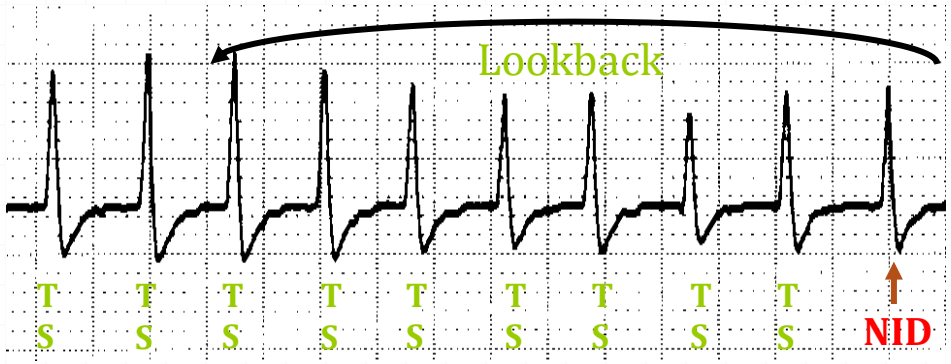
Template

QRS waveform

Normal Sinus

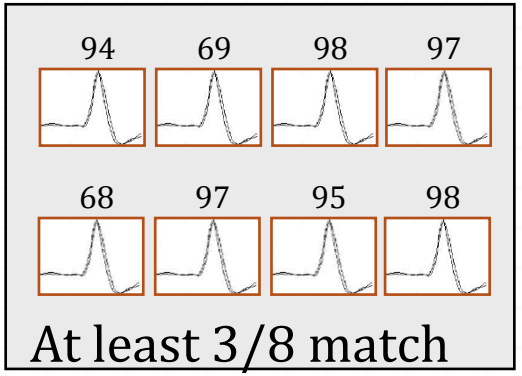


Withhold Therapy!



Wavelet

Match Threshold 70%



At least 3/8 match

: SVT

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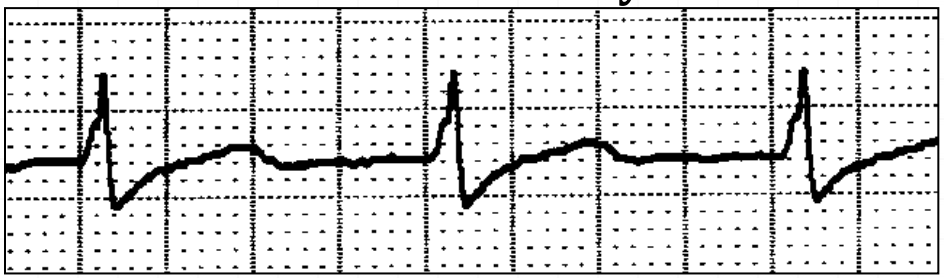
Wavelet Template Matching - Marquis VR

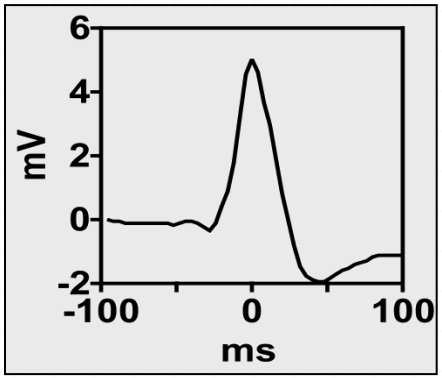
Intrinsic Normal Rhythm

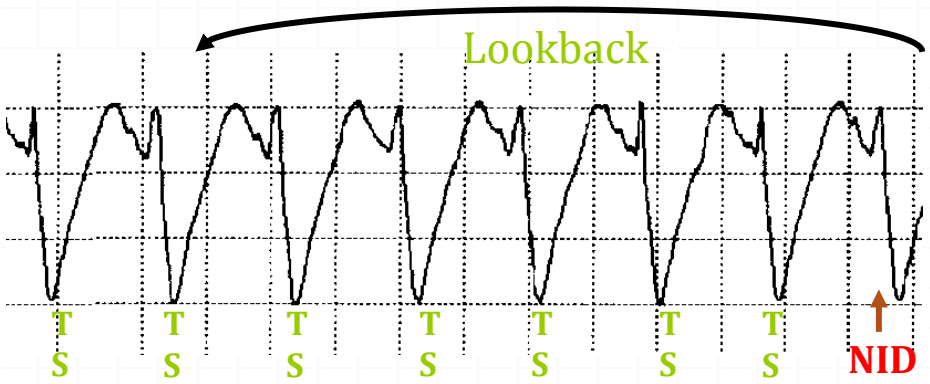


Create

Template

Normal Sinus

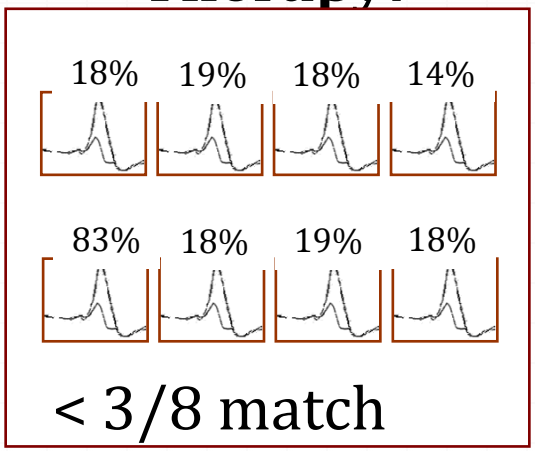




Wavelet

Match Threshold 70%

Deliver Therapy!



< 3/8 match

: VT/VF

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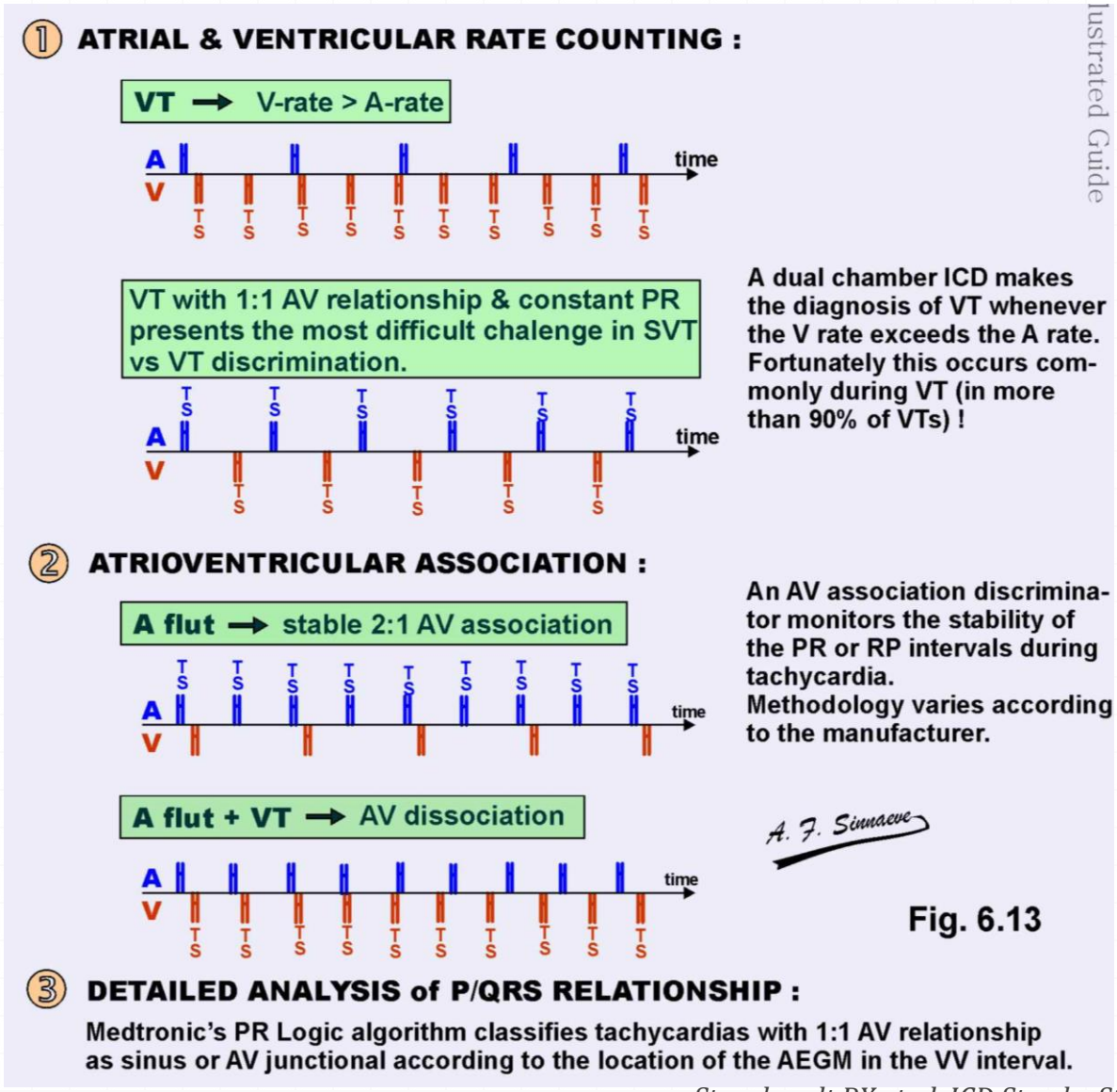
Dual Chamber Discriminator



Stroobandt RX et al. ICD Step by Step – An illustrated Guide

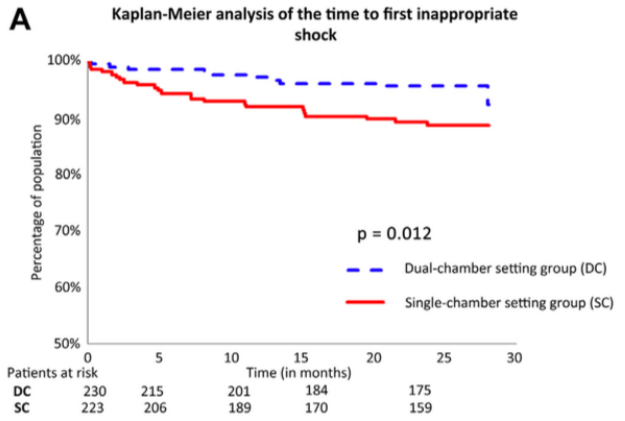
Single vs. Dual Chamber ICD

TABLE 1 Baseline Characteristics of the Study Population

Variable	Dual-Chamber Setting Group (n = 230)	Single-Chamber Setting Group (n = 223)
Age (yrs)	62.6 ± 10.9	63.9 ± 10.0
Men	186 (85.3%)	189 (86.7%)
Implantation indication		
Primary prevention	168 (73.7%)	171 (76.7%)
Secondary prevention	60 (26.3%)	52 (23.3%)
NYHA functional class I/II/III/IV	16%/62/21%/1%	14%/67%/18%/1%
LVEF (%)	29.7 ± 8.5	28.3 ± 7.6
Cardiac disease		
Coronary	173 (75.5%)	173 (77.6%)
Cardiomyopathy	79 (34.5%)	84 (37.7%)
QRS duration (ms)	111.0 ± 25.1	111.2 ± 28.3
Conduction disorders		
AV block	41 (17.9%)	32 (14.3%)
Bundle-branch block	36 (15.7%)	43 (19.3%)
Atrial rhythm disorder		
Paroxysmal atrial flutter	11 (4.8%)	2 (0.9%)
Atrial tachycardia	2 (0.9%)	6 (2.7%)
Paroxysmal atrial fibrillation	24 (10.5%)	25 (11.2%)
Associated conditions		
Arterial hypertension	85 (37.1%)	96 (43.0%)
Diabetes	48 (21.0%)	53 (23.8%)
Drugs		
Beta-blockers	186 (84.9%)	173 (82.0%)
ACE inhibitors/ARBs	178 (81.3%)	164 (77.7%)
Spironolactone	57 (26.0%)	45 (21.3)
Class III antiarrhythmic agents	26 (11.9%)	24 (11.4%)

Values are mean ± SD or n (%). Differences between the groups were not statistically significant.

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; AV = atrioventricular; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.



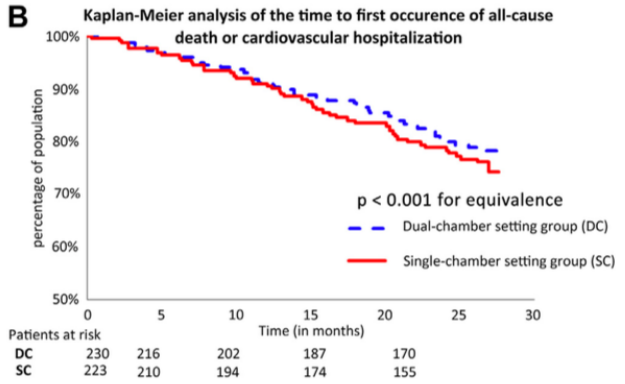


FIGURE 2 Time to First Inappropriate Shock and to First Occurrence of All-Cause Death or Cardiovascular Hospitalization

Kaplan-Meier analysis of **(A)** time to first inappropriate shock and **(B)** time to first occurrence of all-cause death or cardiovascular hospitalization in patients with dual-chamber (DC) settings **(blue dotted line)** and single-chamber (SC) settings **(red line)**.

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Kolb C et al. JACC Heart Fail. 2014;2:611-9.

Single vs. Dual Chamber ICD

TABLE 4 Reasons for Inappropriate Shocks in the 2 Treatment Groups

Variable	Total (n = 453)	Dual-Chamber Setting Group (n = 230)	Single-Chamber Setting Group (n = 223)
Number of inappropriate shocks	106	24	82
SVT	78 (73.6%)	7 (29.2%)	71 (86.6%)
Lead failure/oversensing	27 (25.5%)	17 (70.8%)	10 (12.2%)
Reason unknown	1 (0.9%)	0	1 (1.2%)

Values are n (%).

SVT = supraventricular tachyarrhythmia.

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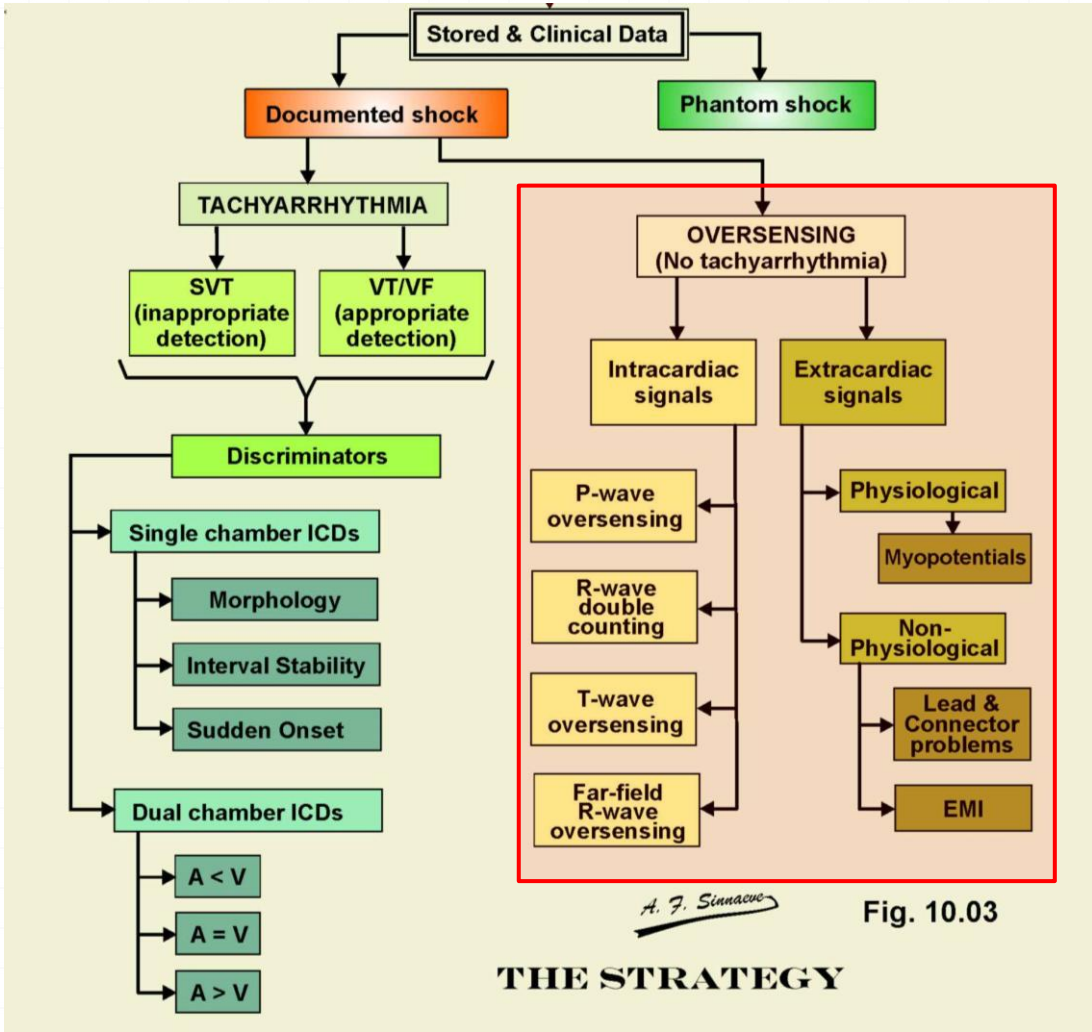
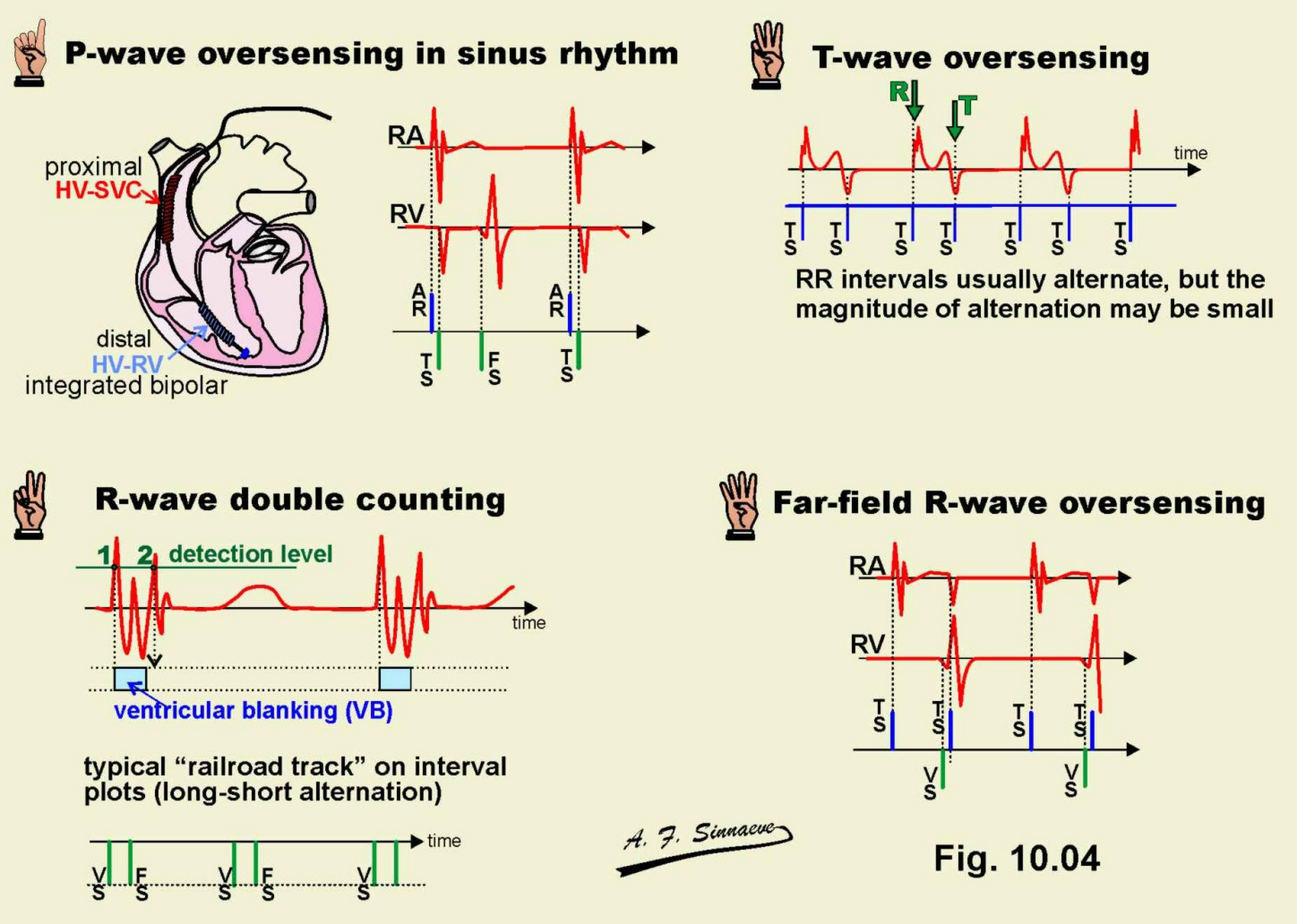
Kolb C et al. JACC Heart Fail. 2014;2:611-9.

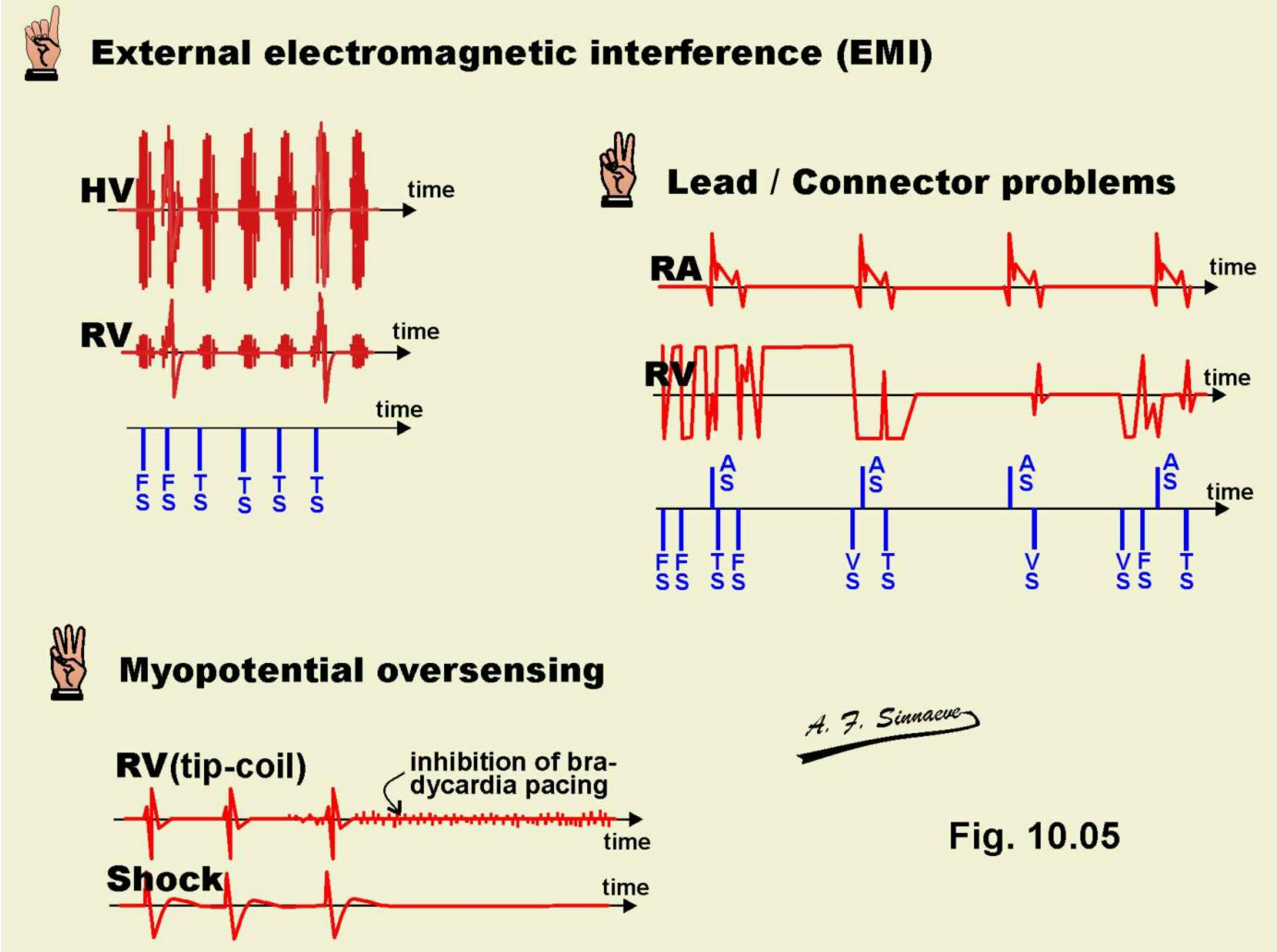
Oversensing



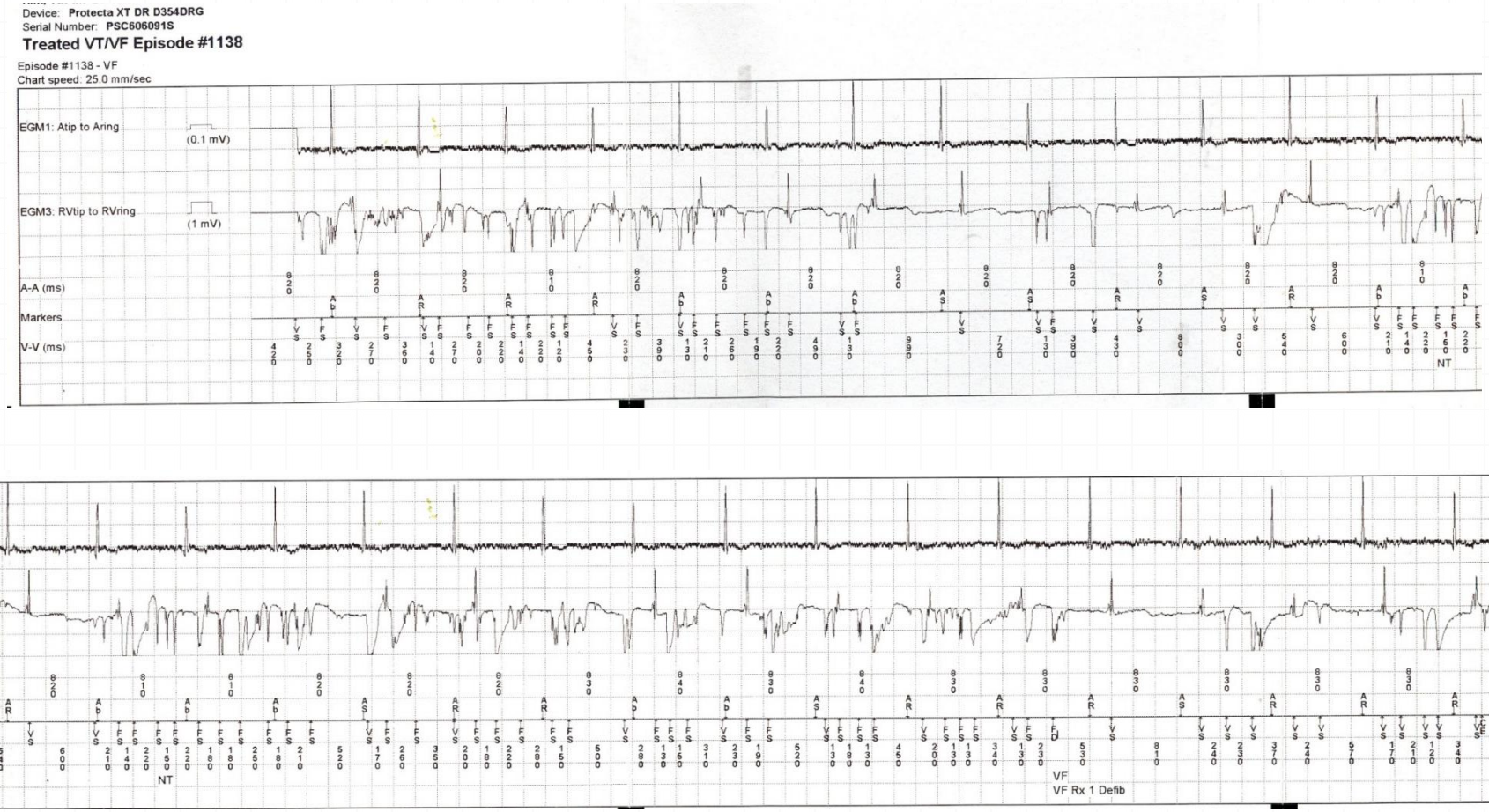
Oversensing of Intracardiac Signals



Oversensing of Intracardiac Signals

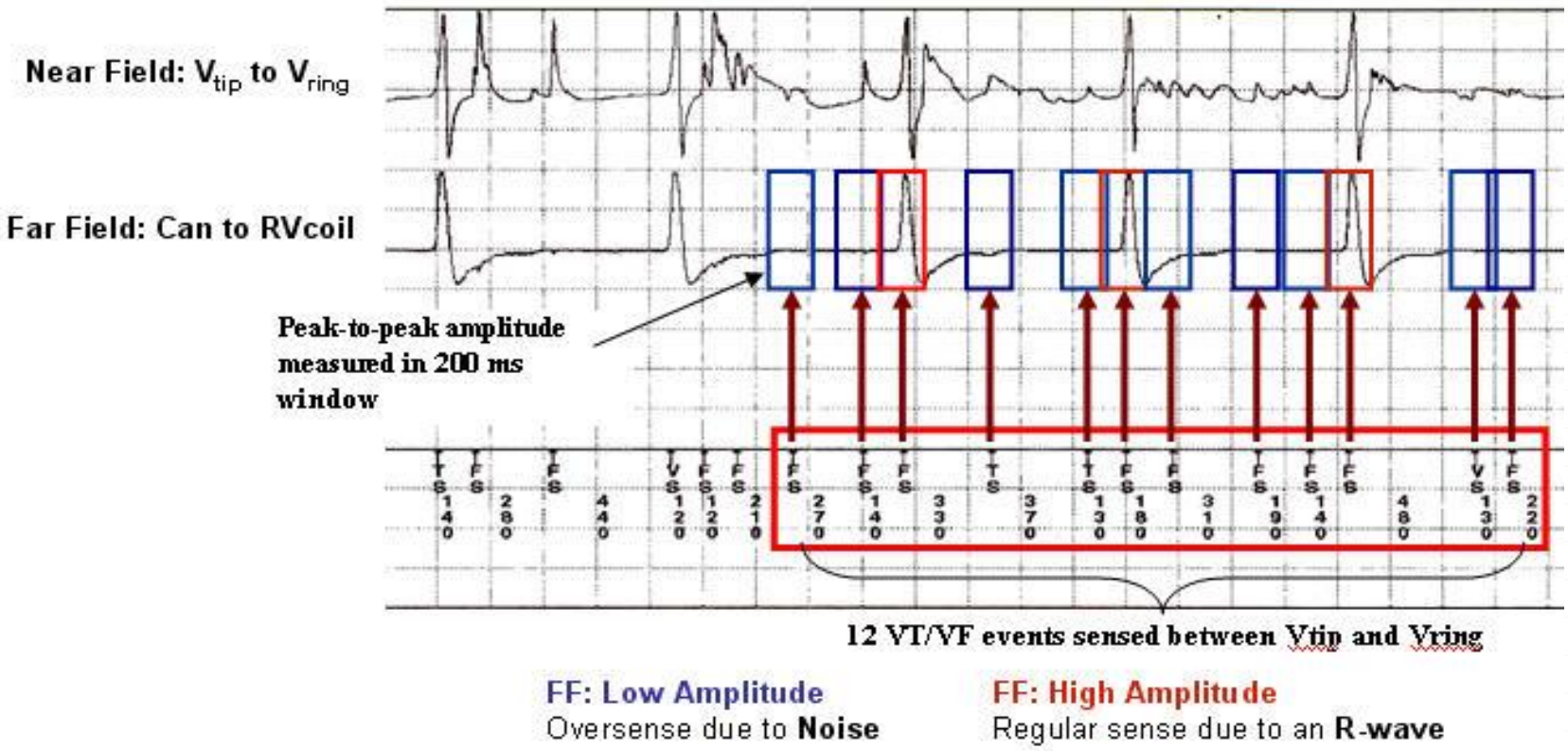


Lead Fracture : Noise sensing & Shock



RV Lead Noise Discriminator

- Lead noise oversensing is typically isolated to the near-field sensing signal
- Analyzing far-field EGM to validate near-field sensing
- Timeout setting: 45sec (85% episode<45sec)



Summary : Recommendations

- Detection duration - for at least 6-12 sec or for 30 intervals
- Slowest tachycardia therapy zone in primary prevention
  - between 185-200 bpm
- Slowest tachycardia therapy zone in secondary prevention
  - at least 10 bpm below documented rate but not faster than 200 bpm.
- Activate discrimination algorithms to distinguish SVT from VT
- Activate lead-failure alerts and lead "noise" algorithms
- Program more than one tachycardia detection zone
- Choose single-chamber ICD if the reason for atrial lead is SVT discrimination
- Activate T-wave oversensing algorithms

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Wilkoff BL et al. Heart Rhythm. 2016;13:e50-86.

Summary : Recommendations

- Activate ATP therapy for all detection zones
- At least 1 ATP attempt with minimum of 8 stimuli and a CL of 84%-88% of TCL
- Burst ATP therapy in preference to ramp ATP therapy
- Activate shock therapy in all therapy zones
- Program initial shock energy to the maximum available energy in the highest rate detection zone

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Wilkoff BL et al. Heart Rhythm. 2016;13:e50-86.

Thanks for your attention !!

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