Reducing unnecessary and inappropriate therapy in secondary prevention patients

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Goals of Optimal ICD Programming

- Ensure detection and effective therapy for life-threatening VT/VF.

Sorry

- ↓ unnecessary shocks
  - ↓↓ inappropriate Rx for SVT.
  - ↓↓ inappropriate Rx for oversensing.
  - ↓↓ unecessary Rx for self-terminating VT.
  - Terminate VT/VF with ATP whenever possible.
  - Prevent proarrhythmia.

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Are there specific features for secondary prevention patients ?

→ SP pts : unique clinical characteristics with more arrhythmic profile

→ In the recent ICD era , implanted population moved from secondary indication to HF PP indication … Very few studies on SP

→ Which strategies to ↓ unncessary and inappropriate therapies in SP ?

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Possible strategies to ↓ unnecessary and inappropriate therapies in SP

1. Choice of ICD

2. Choice of device programming

1. ICD : VVI versus DDD

HLC 1992 No. of Pages 7

ARTICLE IN PRESS

Heart, Lung and Circulation (2015) xx, 1–7
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ORIGINAL ARTICLE

Efficiencies and Complications of Dual Chamber versus Single Chamber Implantable Cardioverter Defibrillators in Secondary Sudden Cardiac Death Prevention: A Meta-analysis

Zuo-Ying Hu, MD PhD[1], Juan Zhang, MD[1], Zhou-Tao Xu, MD[1],
Xiao-Fei Gao, MD, Hang Zhang, MD, Chang Pan, MD,
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Figure 3 Forest plot for appropriate therapy.

No differences in inappropriate/appropriate shocks
in DDD vs VVI ICD
in secondary prevention

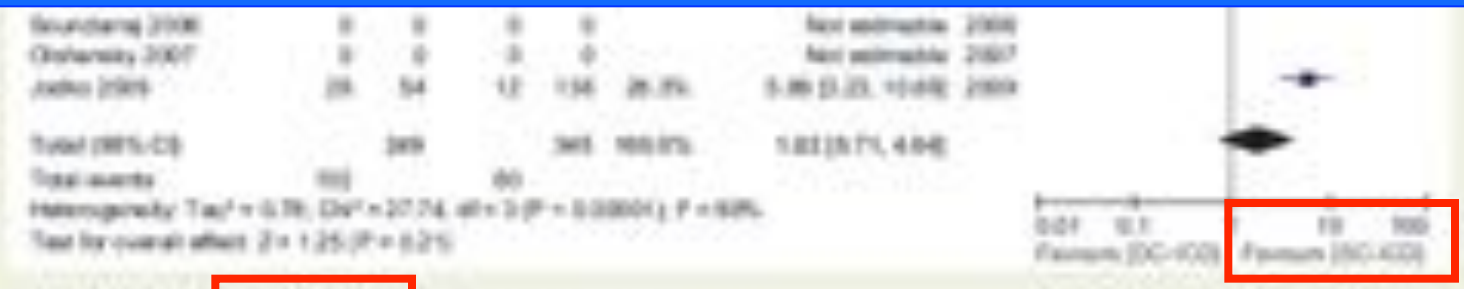
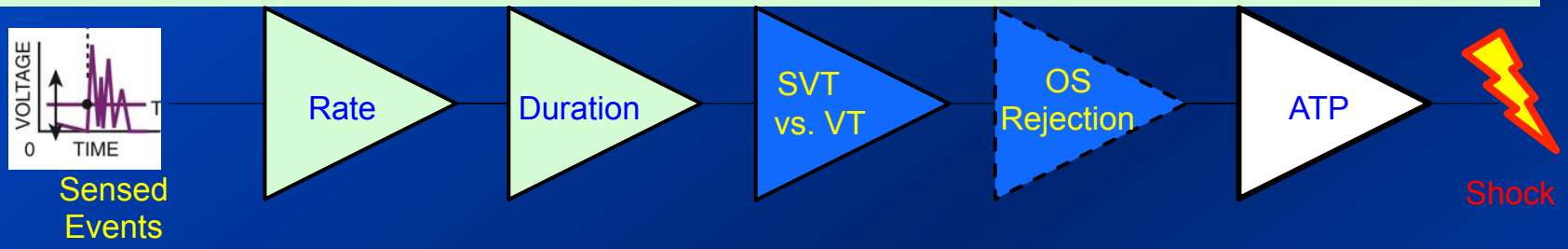


Figure 4 Forest plot for inappropriate detection of SVT.

2. ICD : device programming

Clinical Trials of Features to Minimize Shocks



	Faster Rate	Longer Duration	SVT-VT Discrimination	Sensing Confirmation	ATP
PREPARE (2008)	X	X	(X)		X
RELEVANT (2009)		X	x		X
MADIT-RIT (2012)	X	X†	X†		X
ADVANCE III (2013)*		X	X		X
PROVIDE (2014)	X	X	X		X
PAINFREE SST (2015)*	X	X	X	X	X

* Included secondary prevention patients.

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Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results

Angelo Auricchio, MD, PhD,* Edward J. Schloss, MD, FHRS,† Takashi Kurita, MD,‡ Albert Meijer, MD,§ Bart Gerritse, PhD,¶ Steven Zweibel, MD, FHRS,‖ Faisal M. AlSmadi, MD, FHRS,** Charles T. Leng, MD,†† Laurence D. Sterns, MD‡‡ on behalf of the PainFree SST Investigators

From the *Fondazione Cardiocentro Ticino, Lugano, Switzerland, †The Christ Hospital/The Ohio Heart & Vascular Center, Cincinnati, Ohio, ‡Kinki University School of Medicine, Osaka, Japan, §Catharina Ziekenhuis, Eindhoven, The Netherlands, ¶Medtronic Bakken Research Center, Maastricht, The Netherlands, ‖Hartford Hospital, Hartford, Connecticut, **Prince Salman Heart Centre–King Fahad Medical City, Riyadh, Saudi Arabia, ††University of Pennsylvania, Philadelphia, Pennsylvania, and ‡‡Royal Jubilee Hospital, Victoria, Canada.

(Heart Rhythm 2015;12:926–936)

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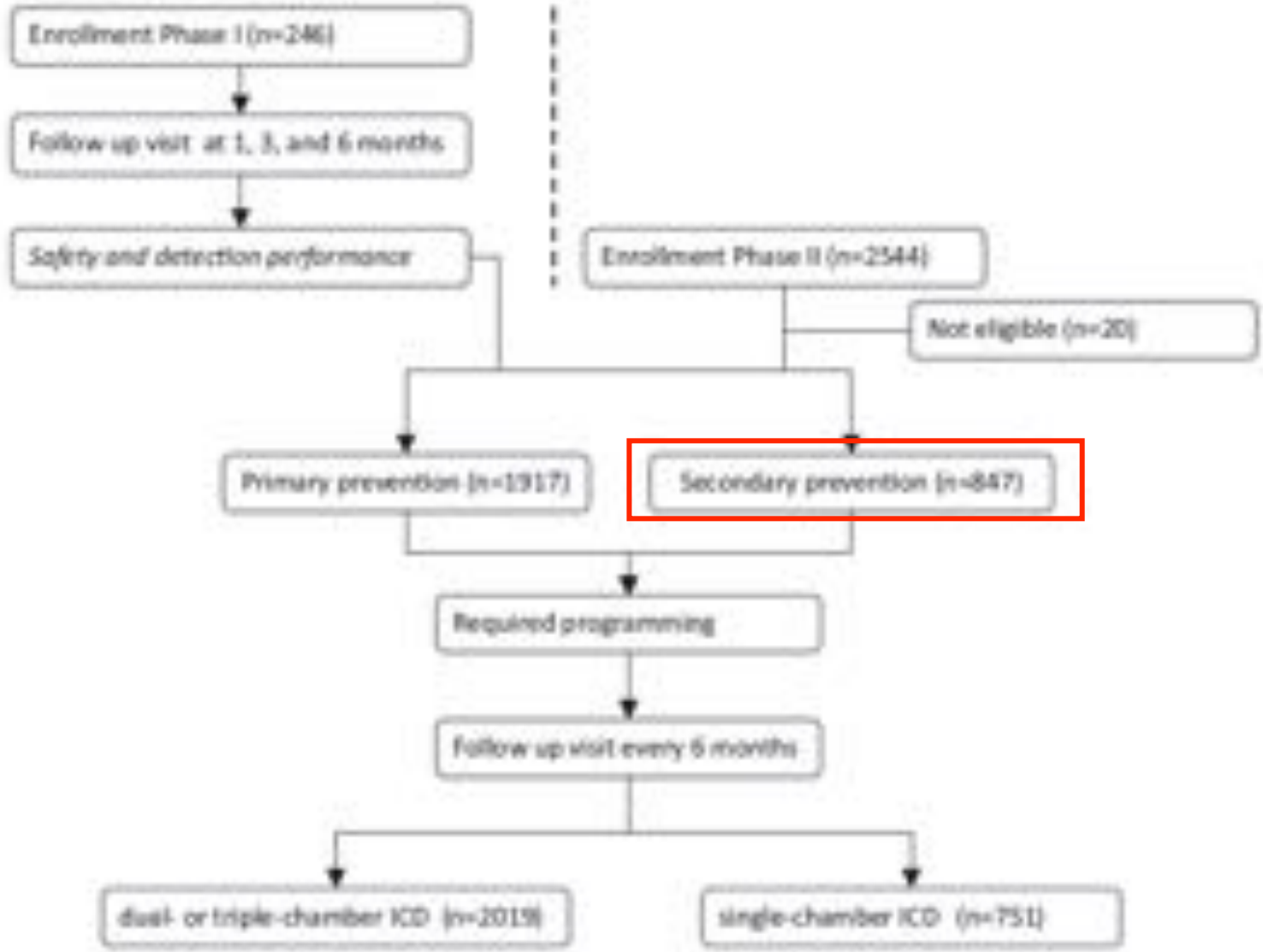

Figure 1 Flow diagram.

Extremely low incidence of inappropriate shocks

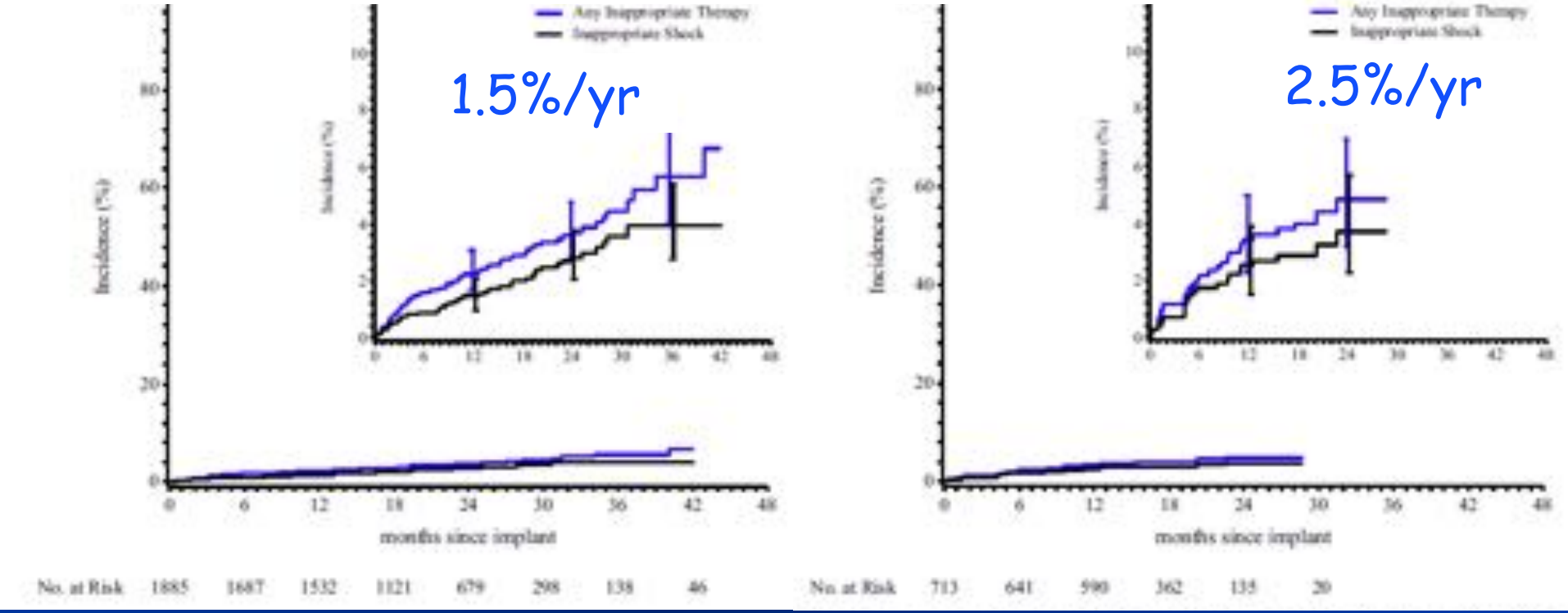

Figure 2 Inappropriate shocks and inappropriate therapy in dual/triple-chamber devices (A) and single-chamber devices (B). The main figure and the inset show the same curves on a different scale in both panels.

→ Absence of a control group in the general population !

→ Waiting for results in SP …

The secondary prevention patients were randomized between NID 30/40 and 18/24 with further analysis to be reported at a later time.

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RELEVANT (2009)		X	X		X
MADIT-RIT (2012)	X	X†	X†		X
ADVANCE III (2013)*		X	X		X
PROVIDE (2014)	X	X	X		X
PAINFREE SST (2015)*	X	X	X	X	X

Long detection proven to be effective in PP

Is long detection effective in SP too ?

Efficacy of Long Detection Interval Implantable Cardioverter-Defibrillator Settings in Secondary Prevention Population

Data From the Avoid Delivering Therapies for Nonsustained Arrhythmias in ICD Patients III (ADVANCE III) Trial

Axel Kloppe, MD; Alessandro Proclemer, MD; Angel Arenal, MD; Maurizio Lunati, MD; José Bautista Martinez Ferrer, MD; Ahmad Hersi, MD, MBBS; Marcin Gulaj, MD; Maurits C.E.F. Wijffels, MD, PhD; Elisabetta Santi, MS; Laura Manotta, MS; Lorenza Mangoni, MS; Maurizio Gasparini, MD

(*Circulation*. 2014;130:308-314.)

(ADVANCE III) Trial

Table 1. Baseline Patient Characteristics

	18/24 NID (n=248)	30/40 NID (n=229)	All (n=477)
Patient demographics			
Age, mean (SD)	65 (12)	65 (13)	65 (12)
Male sex*	221 (89)	184 (80)	405 (85)
Medical history			
VF/ventricular flutter	92 (37)	82 (36)	174 (37)
Sustained VT history	160 (65)	146 (64)	306 (64)
Permanent AF	21 (9)	24 (11)	45 (10)
NYHA class III or IV	74 (30)	65 (29)	139 (30)
Angina	36 (15)	31 (14)	67 (14)
Hypertension	145 (59)	116 (51)	261 (55)
Coronary artery disease	151 (61)	131 (57)	282 (59)
History of syncope	131 (53)	118 (52)	249 (52)
Previous revascularization	104 (42)	90 (39)	194 (41)
QRS, ms, mean (SD)	117 (32)	117 (37)	117 (34)
LBBB	47 (19.)	45 (20)	92 (19)
Hypercholesterolemia	133 (54)	118 (52)	251 (53)
Diabetes mellitus	63 (25)	45 (20)	108 (23)
Chronic kidney disease	28 (11)	25 (11)	53 (11)

(*Circulation*. 2014;130:308-314.)

(ADVANCE III) Trial

Baseline echocardiographic measures			
Moderate/severe MR	15 (11)	14 (12)	28 (12)
LVEF, %, mean (SD)	38 (14)	39 (13)	38 (14)
LVDD, mm, mean (SD)	60 (10)	59 (10)	60 (10)
Baseline medications			
Antiarrhythmic agent	92 (37)	81 (35)	173 (36)
β-Blocker	197 (79)	173 (76)	370 (78)
Implanted device			
Single-chamber	90 (36)	85 (37)	175 (37)
Dual-chamber	117 (47)	109 (48)	226 (47)
CRTD	41 (17)	35 (15)	76 (16)

SP population is obviously more "arrhythmic" then HF …

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(ADVANCE III) Trial

Results

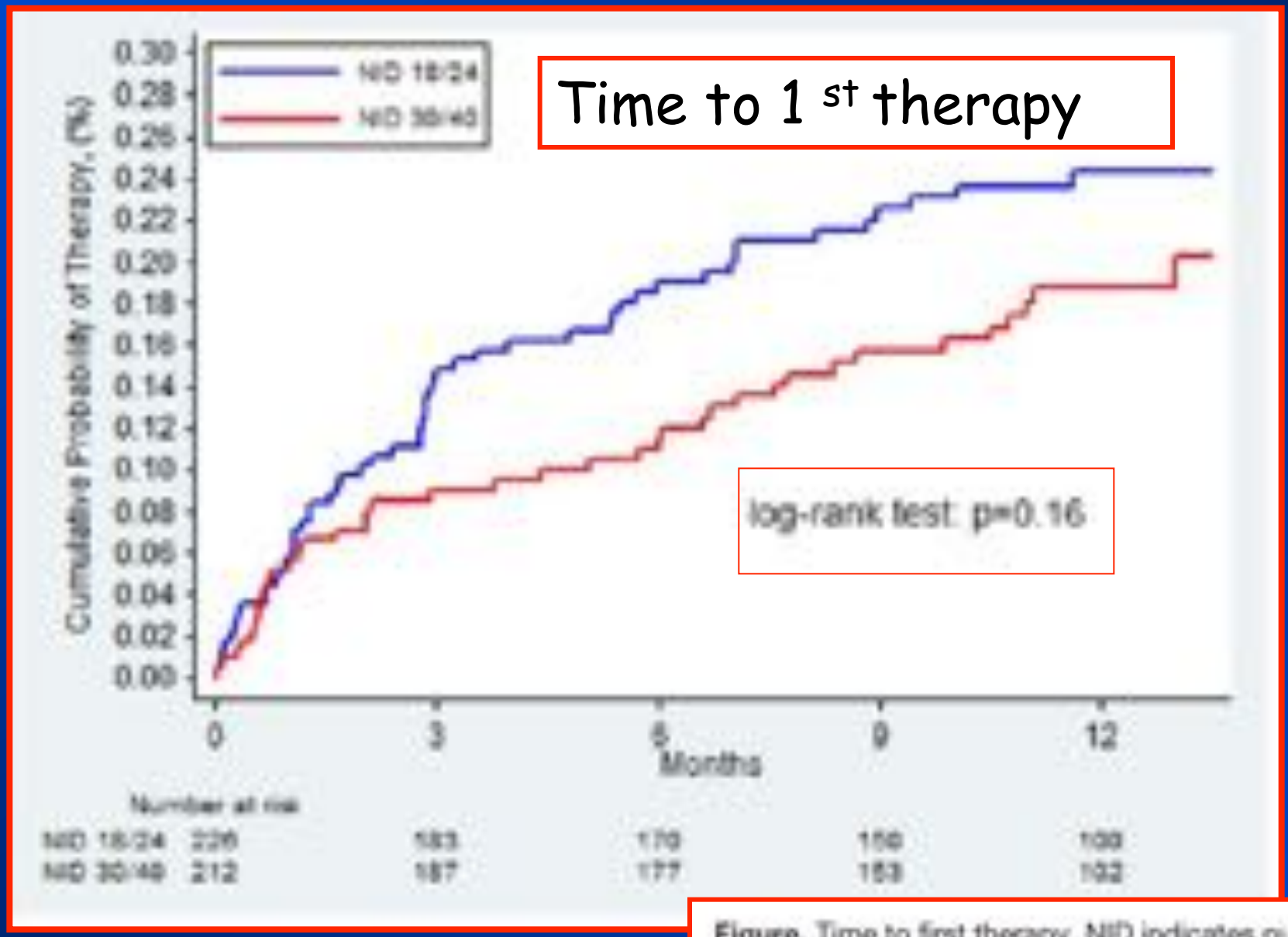

Figure. Time to first therapy. NID indicates number of intervals to detect ventricular fibrillation.

(ADVANCE III) Trial

Results

Table 2. Results of Delivered ICD Therapies According to Intention-to-Treat Analysis

Therapies	Detection Window NID	No. of Therapies (No. of Treated Episodes)	Therapy Rate per 100 Patient-Years	IRR (95% CI)	*P* Value
Overall	18/24	246 (134)	115.6 (101.6–130.9)	1	0.008
	30/40	173 (92)	86.8 (74.3–100.7)	0.75 (0.61–0.93)	
ATP	18/24	137 (124)	55.0 (54.0–76.1)	1	0.24
	30/40	97 (83)	48.7 (39.5–59.4)	0.85 (0.64–1.12)	
Shock	18/24	109 (68)	51.2 (42.0–61.8)	1	0.007
	30/40	76 (58)	38.1 (30.0–47.7)	0.66 (0.48–0.89)	

Episodes considered in Table 2 are not mutually exclusive. Of the total 226 episodes recorded, 100 episodes received only ATP, 19 received only shock, and 107 received both ATP and shock. ATP indicates antitachycardia pacing; CI, confidence interval; ICD, implantable cardioverter-defibrillator; IRR, incidence rate ratio; and NID, number of intervals to detect ventricular fibrillation.

Long detection in SP : ↓ 25 % ALL therapy

Long detection in SP : ↓ 34 % SHOCKS

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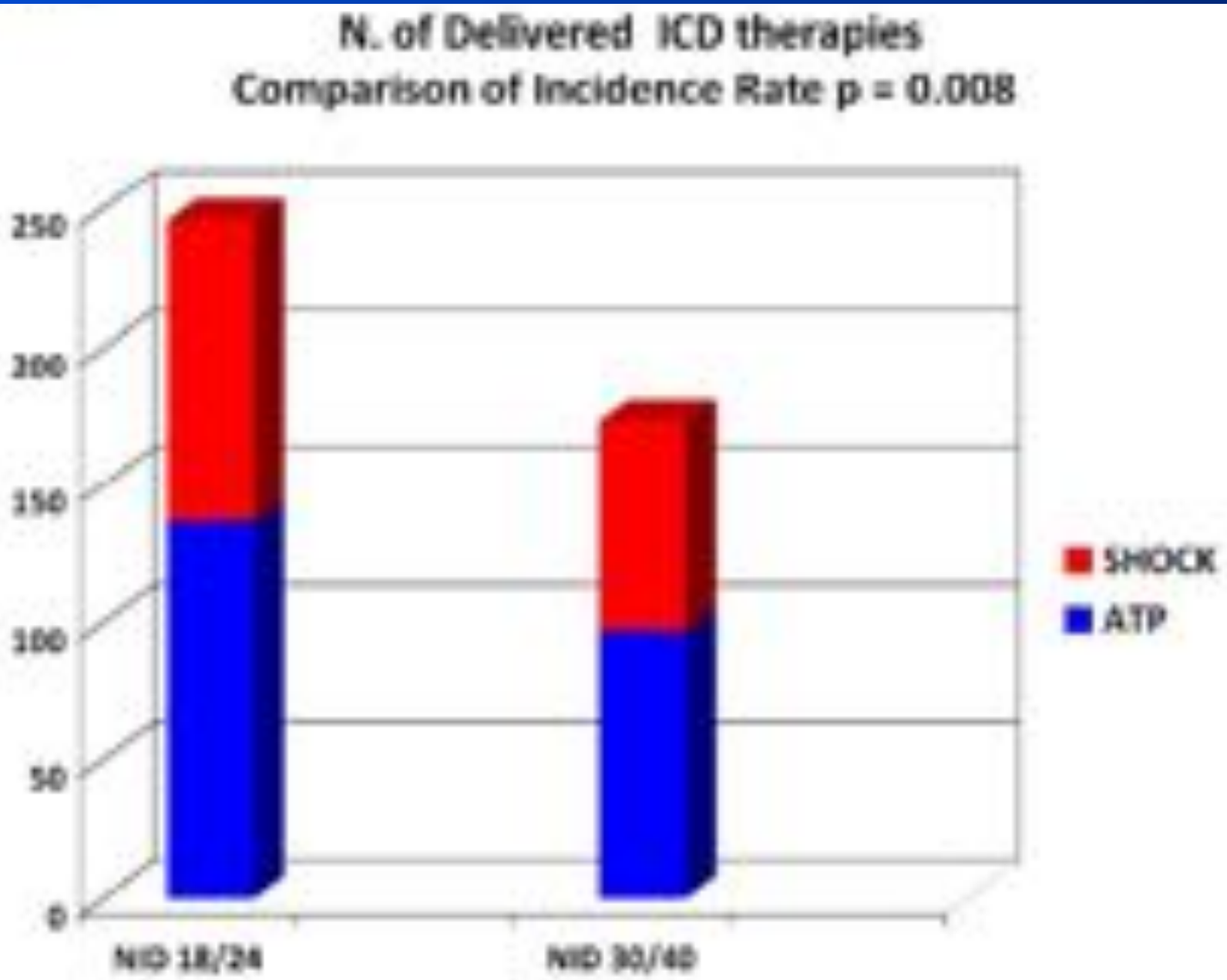

(ADVANCE III) Trial

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				1	0.014
				0.55 (0.34–0.89)	
ATP				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.

(*Circulation*. 2014;130:308-314.)

36% less shocks !!

First time in the Secondary Prevention:

→ ↓ overall therapies and shocks,

→ ↓ APPROPRIATE and INAPPROPRIATE shocks

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First time in the Secondary Prevention:
↓ APPROPRIATE shocks in long detection

In SP too a lot of SELF-TERMINATING TRUE VA !!!

↓ ↓ of APPROPRIATE but UNNECESSARY SHOCKS

QOL ↑↑

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

First time in the Secondary Prevention:
↓ INAPPROPRIATE shocks in long detection

In SP too a lot of SELF-TERMINATING SV ARRYTHMIAS !!!

↓ ↓ of INAPPROPRIATE SHOCKS

QOL ↑↑

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Hypotetical problems long detection-related

Sincopal episodes

Table 4. Safety End Points: Arrhythmic Syncope and All-Cause Death

	Detection Window NID	No. of Syncope Episodes (No. of Patients)	Rate per 100 Patient-Years	IRR (95% CI)	P Value
Arrhythmic syncope	18/24	7 (6)	3.2 (1.3–6.8)	1	0.65
	30/40	4 (3)	2.0 (0.5–5.1)	0.65 (0.11–4.0)	
Death	18/24	16	6.9 (3.9–11.2)	1	0.068
	30/40	12	5.5 (2.8–9.6)	0.80 (0.38–1.69)	

CI indicates confidence interval; IRR, incidence rate ratio; and NID, number of intervals to detect ventricular fibrillation.

→ Syncopal episodes rare,
no difference between 2 arms

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Definitively … According to

Programming and Testing Expert Consensus Statement (HRS/EHRA/APHRS/SOLAECE) Heart Rhythm 2015 in press

Optimal Rate and Duration

	Primary Prevention	Secondary Prevention
Longer Duration	≥ 6-12 s or 30 intervals Class I	≥ 6-12 s or 30 intervals Class I
Detection Rate	185-200 bpm Class I	< VT rate - 10 bpm*& < 200 bpm Class IIA *Or detection interval ≥ VT CL+ 40 ms

For VT window programming: CONSIDER SLOWER CUT OFF RATES if concomitant antiarrhythmic drugs !

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SVT-VT Discrimination Algorithms

Class I Program SVT-VT discrimination algorithms ON for rates up to 200 bpm, potentially up to 230 bpm, unless contraindicated.

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Conclusions

1. Every effort should be made to ↓↓ unnecessary ICD therapies, *especially shocks* (↓↓ QOL and arrhytmogenic risk)

2. Long detection and high rate cut off are well known to reduce appropriate but UNNECESSARY and INAPPROPRIATE therapy in Primary Prevention (Relevant, MADIT RIT, PROVIDE, ADVANCE III)…

3. According to ADVANCE III results long detection programming allows dramatic UNNECESSARY and INAPPROPRIATE shock reduction in SP too

4. Long detection SHOULD BE FIRST- LINE CHOICE *both in Primary and Secondary Prevention*

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