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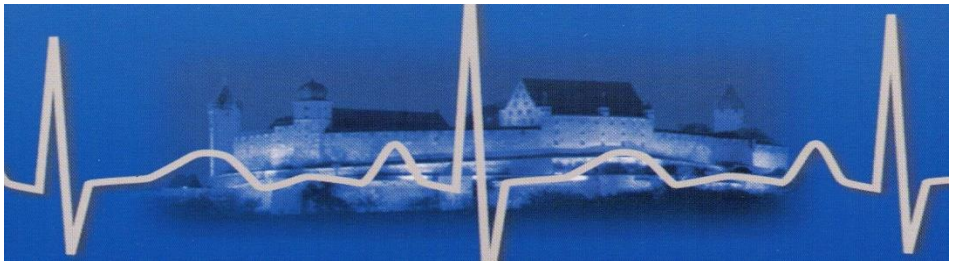

Device-detected Vorhofflimmern: Wann muss antikoaguliert werden?

Prof. Dr. med. J. Brachmann | Stuttgart | 30. Januar 2016

Disclosures

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Speakers bureau, consultant, and/or research support:

- Biotronik, Medtronic, SJM, BSC, Sorin
- Boehringer Ingelheim, Bayer
- Pfizer/Bristol Myers Squibb
- Daiichi Sankyo
- Siemens

Prävalenz von Vorhofflimmern: hoch und zunehmend!

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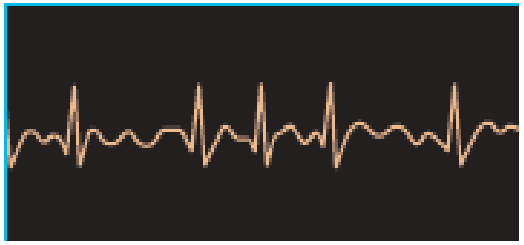
Die am häufigsten anhaltend auftretende kardiale Arrhythmie [1]



https://www.medtronicacademy.com/pdf/could-atrial-fibrillation-be-cause-your-stroke

1,8 Millionen

Menschen in Deutschland leiden an AF[2]

Konsequenzen für die Patienten: [3,4]

- Verringerte Lebensqualität
- Erhöhtes Schlaganfallrisiko
- Erhöhtes Risiko für Herzinsuffizienz

Behandlung

Bei Patienten mit Vorhofflimmern reduzieren Antikoagulantien das Risiko eines Schlaganfalles um 80% und somit ist deren Einnahme unbedingt empfohlen.[5,6,7]

Nach einem nicht-kardioembolischen ischämischen Stroke oder TIA ist Aspirin empfohlen[5,6]

Left Atrial Thrombus in Atrial Fibrillation and Stroke

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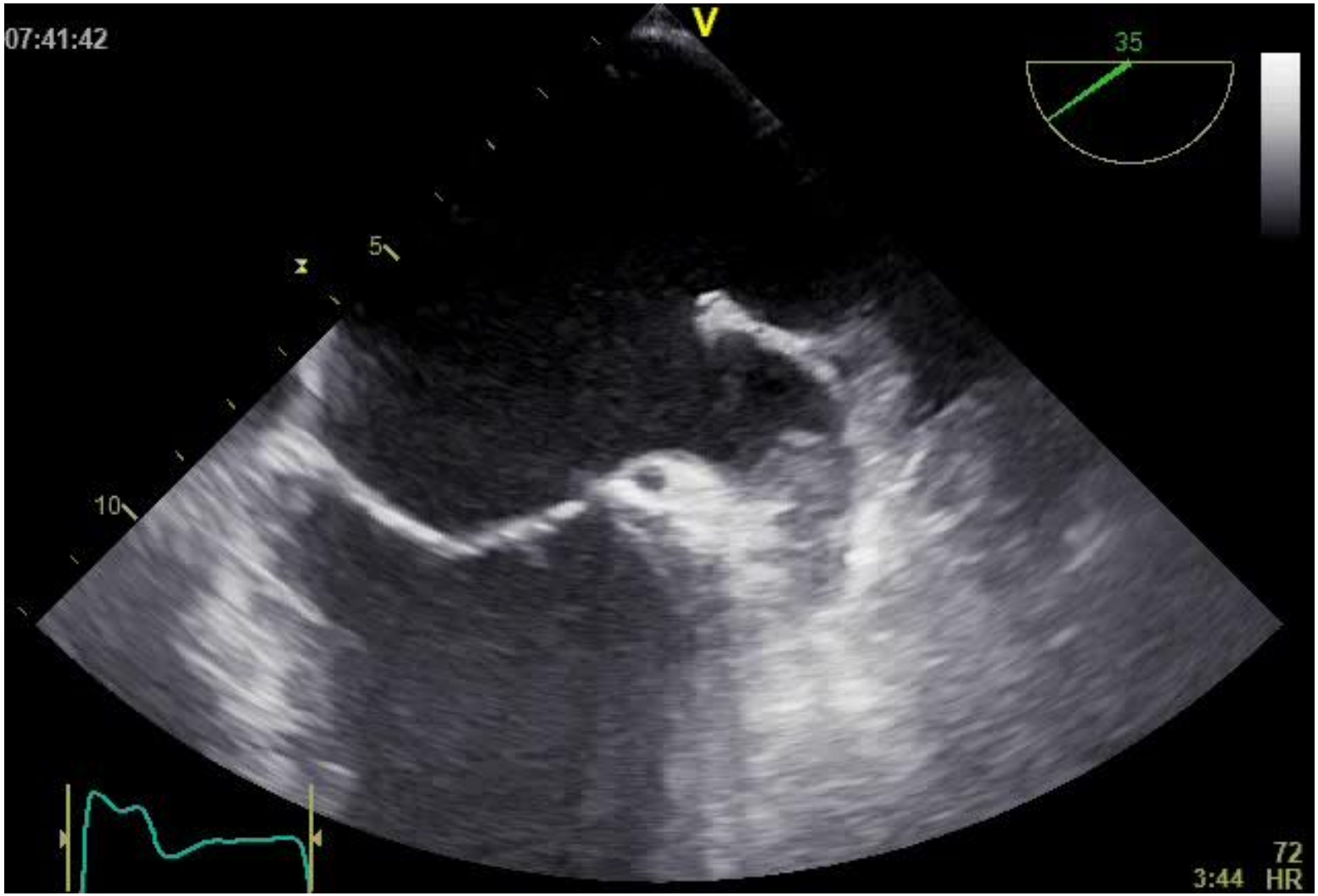

Mechanismus von Schlaganfällen bei Vorhofflimmern

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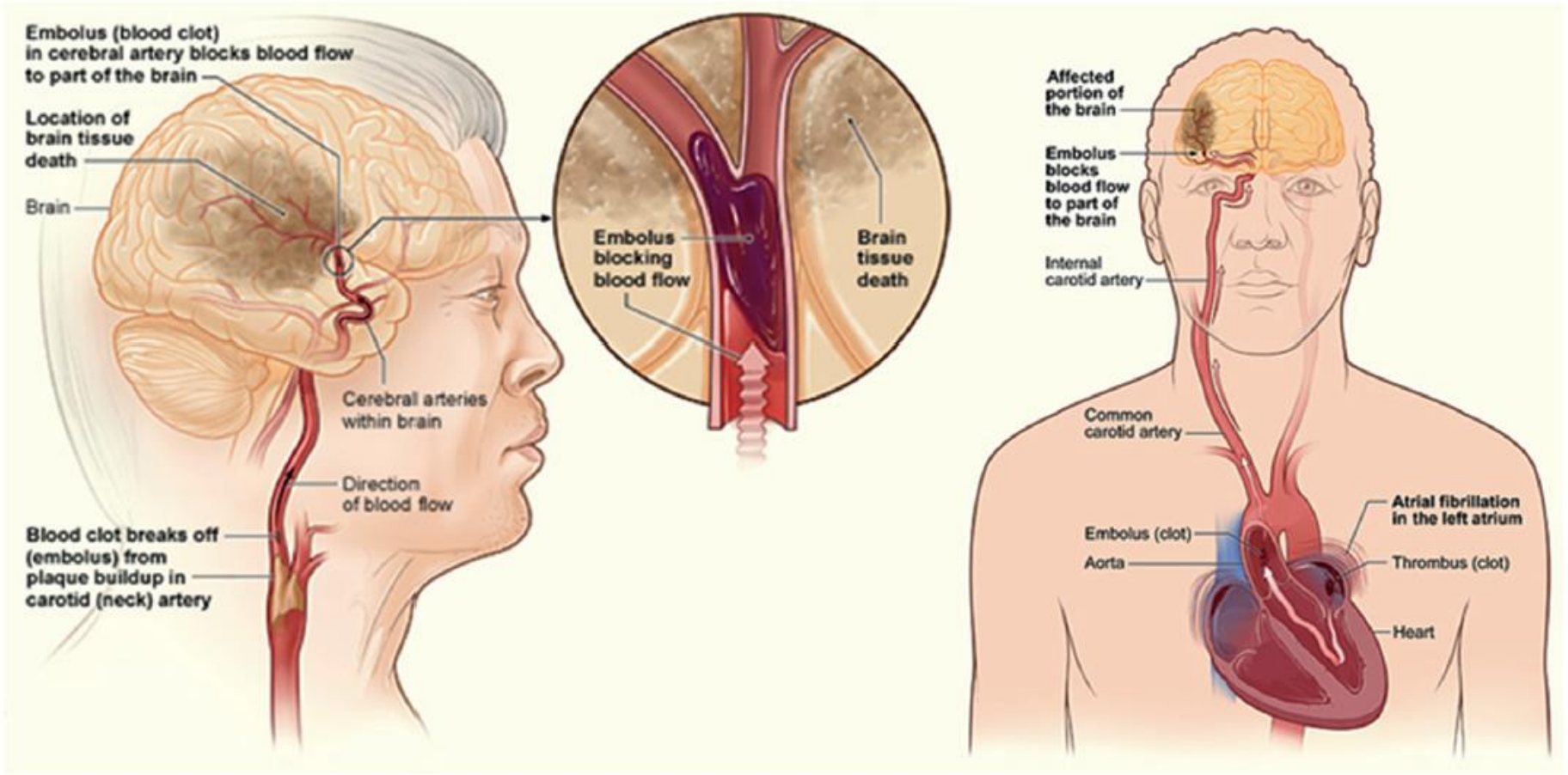

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

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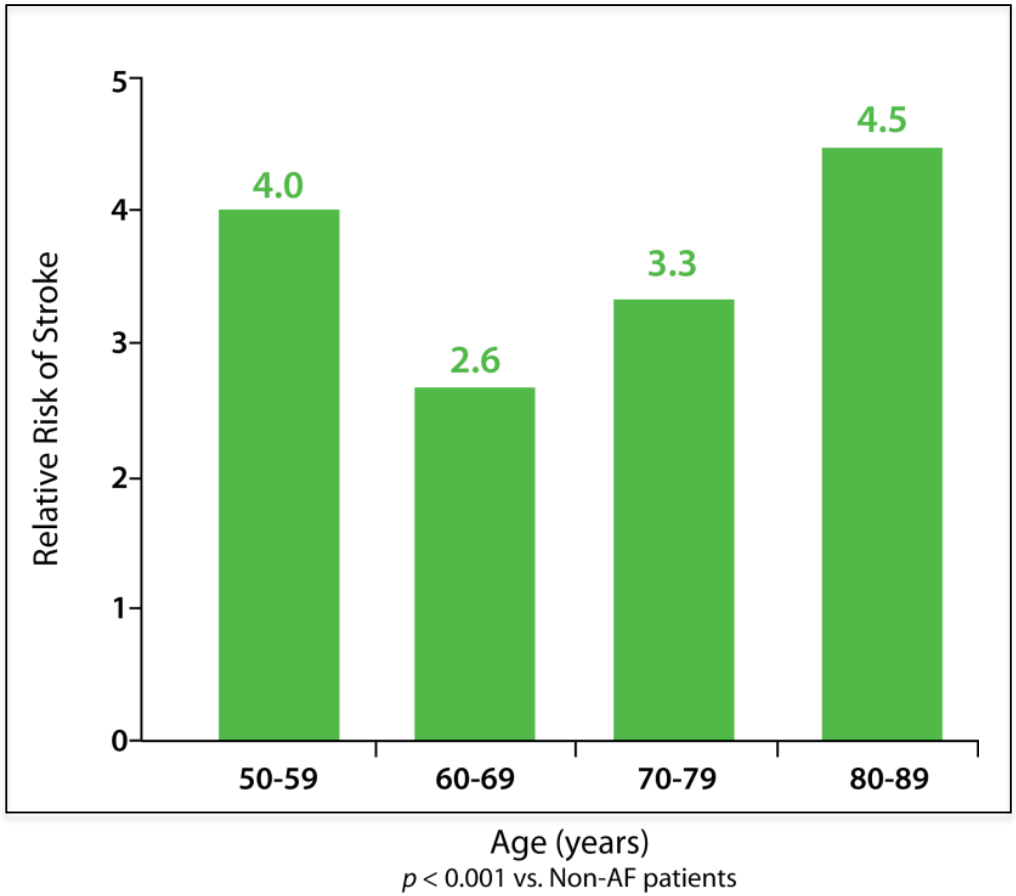
Patienten mit Vorhofflimmern haben ein fast 5-fach erhöhtes Schlaganfallrisiko



Wolff PA, *Stroke.* 1991;22(8):983-988.

Atrial Fibrillation and Stroke

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Atrial Fibrillation increases considerably with age

Age Range	Patients with AF
18-64	9.4%
65-74	20.1%
75-84	28.9%
≥ 85	41.3%

AF is associated with a 5-fold increase risk of stroke

In AF-related strokes:

- **>50% of survivors have severe deficit**
- **Secondary strokes are common and occur at a rate of 12% per year**

Asberg.S. Stroke. June. 2010. Swedish Stroke Register
Lip GYH, Edwards SJ. Thrombosis Res 2006; 118: 321-33
Wolff P et al. Stroke 1991; 22(8):983-988
Mattle HP. Cerebrovasc Dis. 2003;16:3-8

Prävalenz von Vorhofflimmern bei Patienten mit ICD

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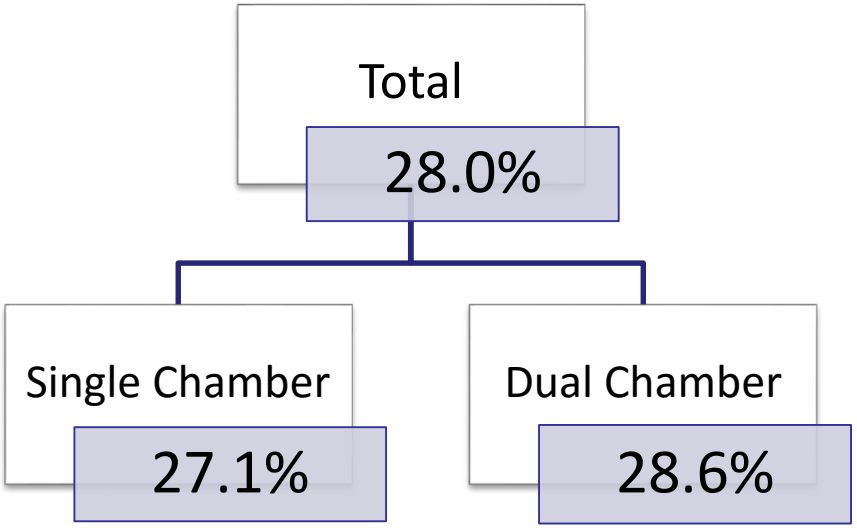
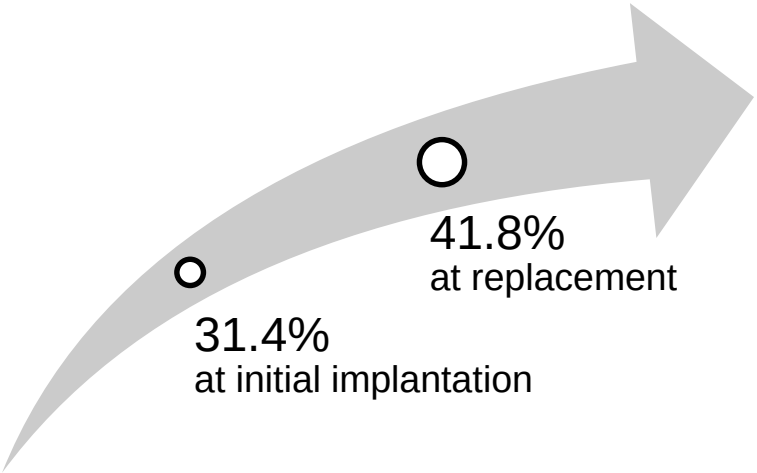
- Mehr als ein Viertel bei jedem Aggregattyp zum Zeitpunkt der Implantation



- BIS zu 42 % zum Zeitpunkt eines Aggregatwechsels



J Am Coll Cardiol 2011;58:1007–13
JAMA. 2013;309(19):2025-2034

Risk of ischaemic stroke according to pattern of atrial fibrillation: analysis of 6563 aspirin-treated patients in ACTIVE-A and AVERROES

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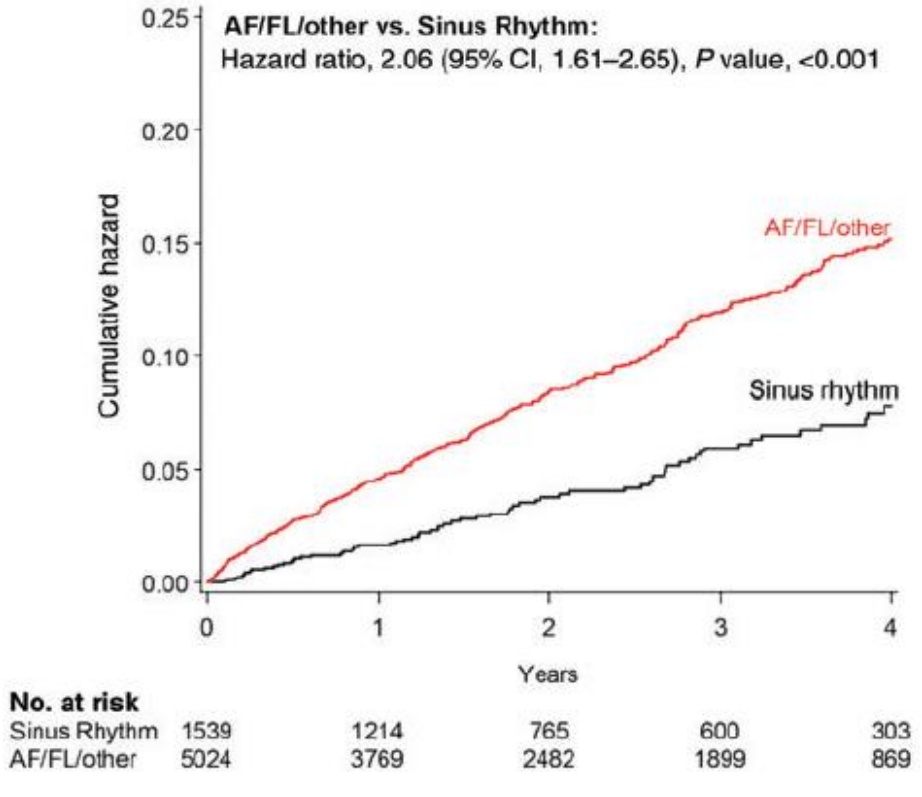
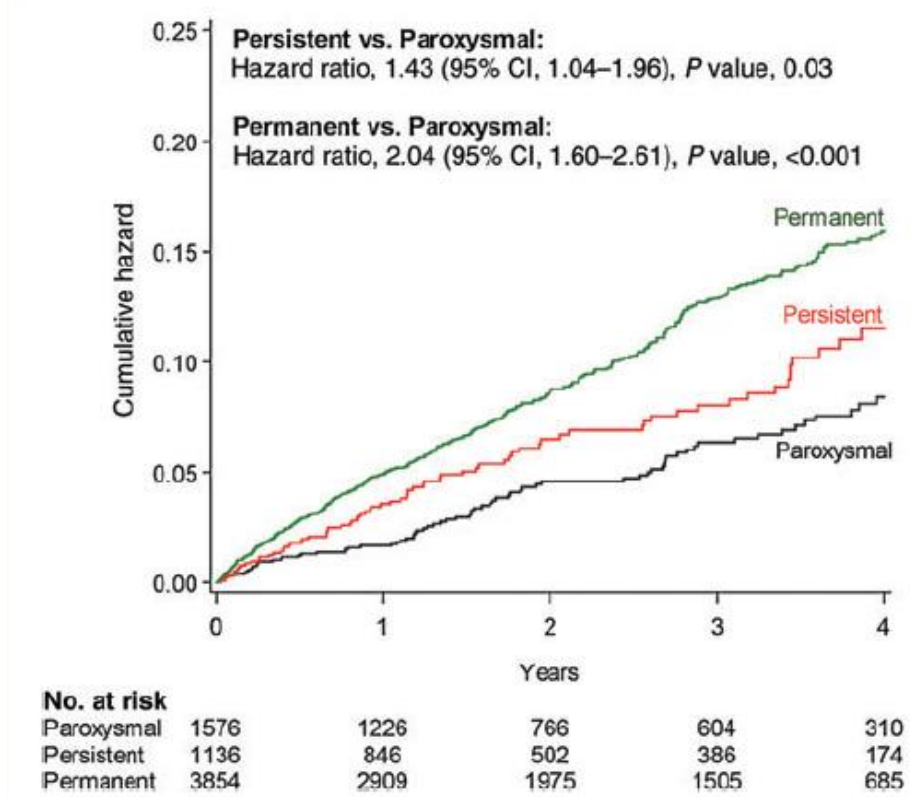
Thomas Vanassche[1]*, Mandy N. Lauw[1], John W. Eikelboom[1], Jeff S. Healey[1], Robert G. Hart[1], Marco Alings[2], Alvaro Avezum[3], Rafael Díaz[4], Stefan H. Hohnloser[5], Basil S. Lewis[6], Olga Shestakovska[1], Jia Wang[1], and Stuart J. Connolly[1]





Vanassche et al; European Heart Journal;2015

Punktewerte der einzelnen Risikokategorien

CHA_2DS_2VASc-SCORE

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Merkmal	Engl. Bezeichnung	Punkte
Herzinsuffizienz	Congestive heart failure	1
Bluthochdruck	Hypertension	1
Alter > 75 Jahre	Age	2
Diabetes mellitus	Diabetes mellitus	1
Vorausgegangener Schlaganfall/TIA*	Stroke/TIA	2
Gefäßerkrankung (z. B. Herzinfarkt)	Vascular disease	1
Alter 65 – 74 Jahre	Age	1
Weibl. Geschlecht (> 65 Jahre)	Sex category	1

Geringes Risiko	Mittleres Risiko	Hohes Risiko
0–1 Punkt	2 Punkte	3–6 Punkte

*TIA = Transitorisch ischämische Attacke

Comparison of Cardiovascular Society Guidelines for OAK in Nonvalvular Atrial Fibrillation

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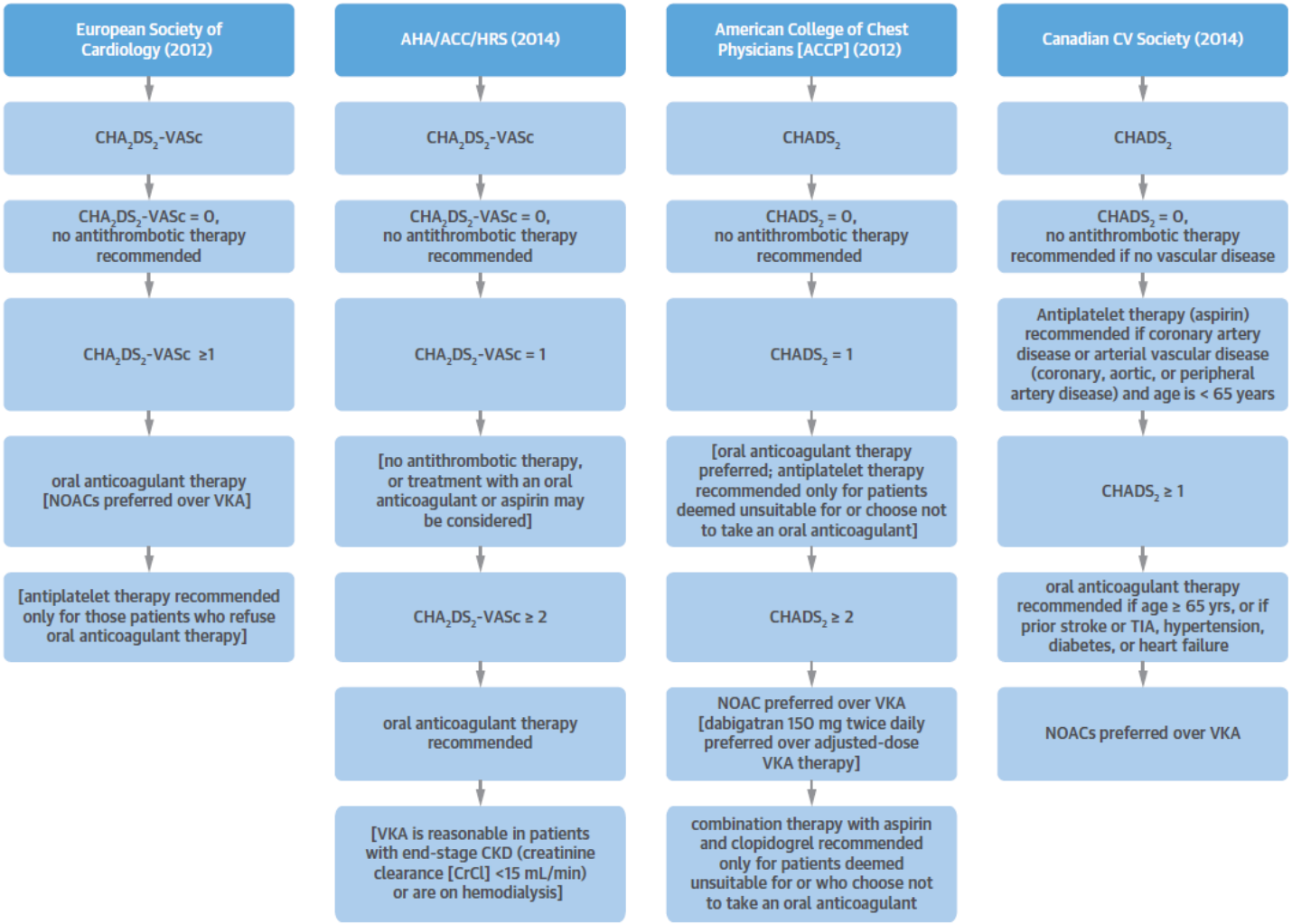

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

Unterschiedliche Zeitlinien bei okkultem Vorhofflimmern

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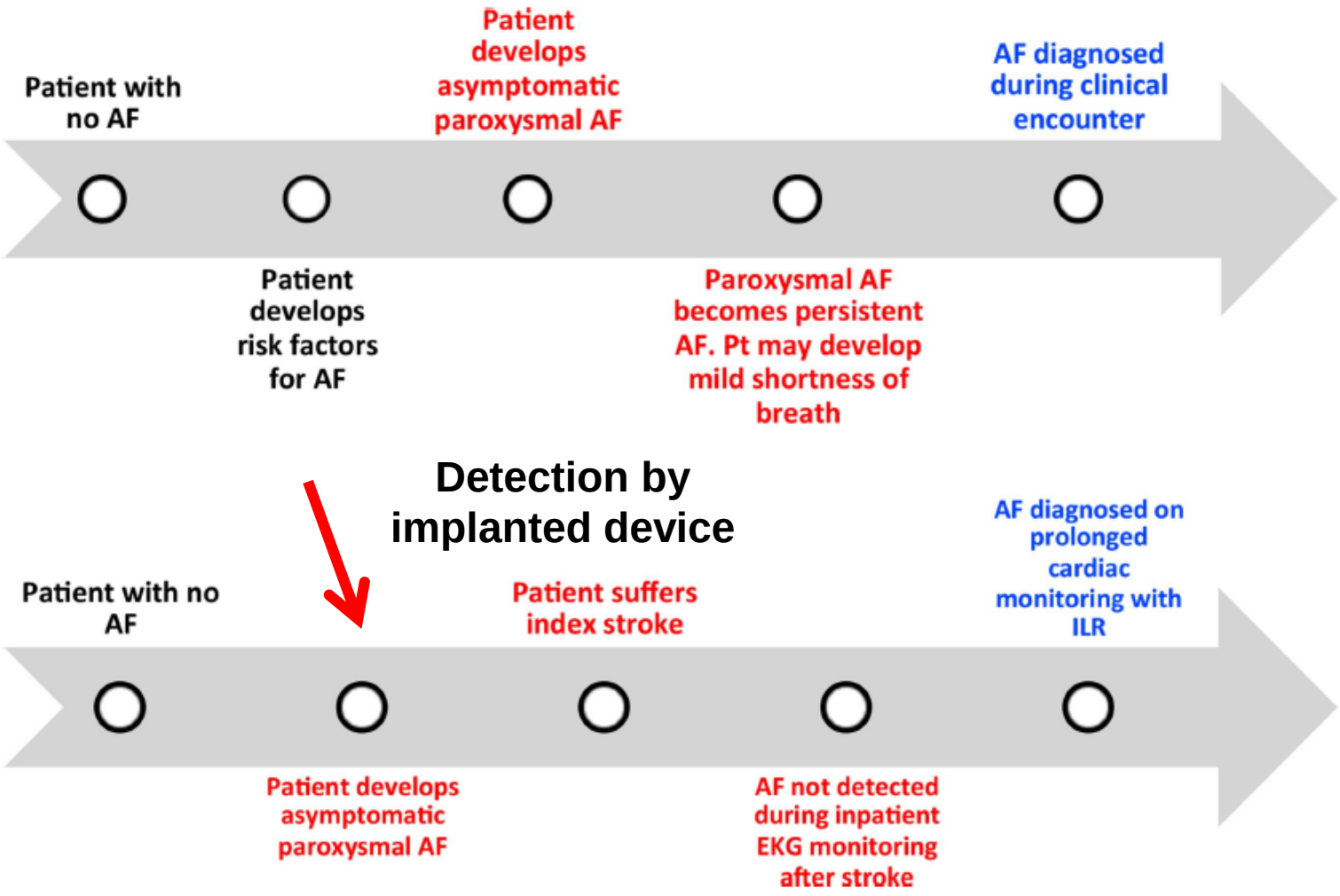

Keach et al. Heart;101:1097–1102,2015

Mögliche Prävention von Schlaganfällen durch Früherkennung von Vorhofflimmern

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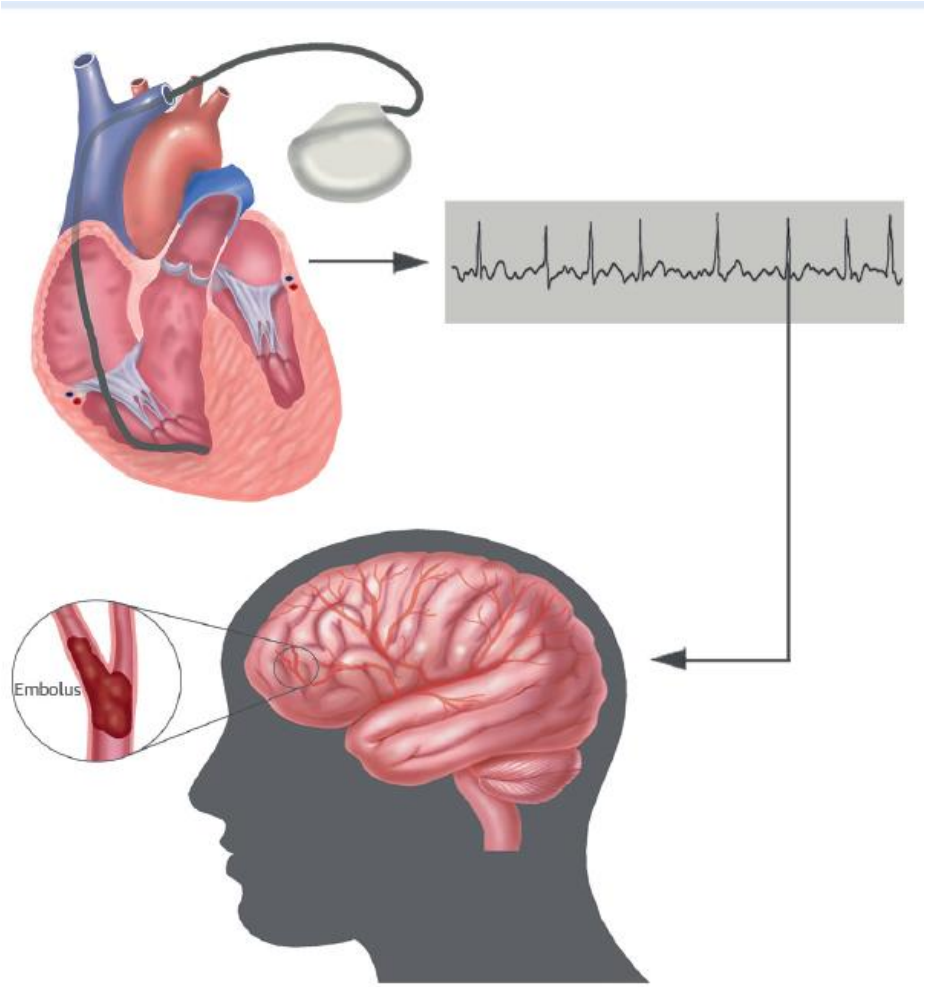

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

Vergleich der Monitoring-Strategien für Vorhofflimmern

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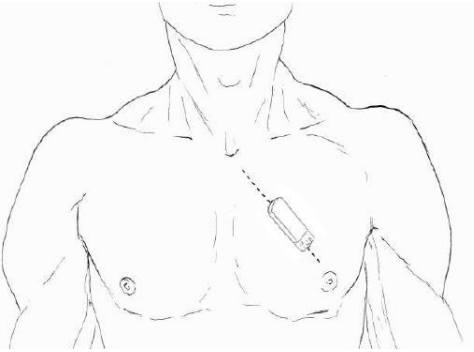

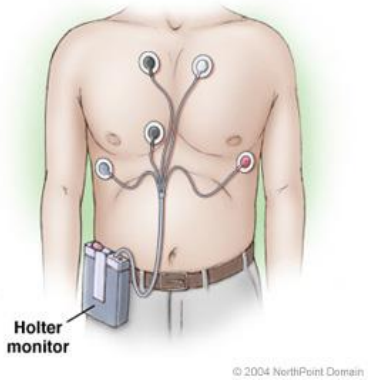

Neuer implantierbarer kardialer Monitor

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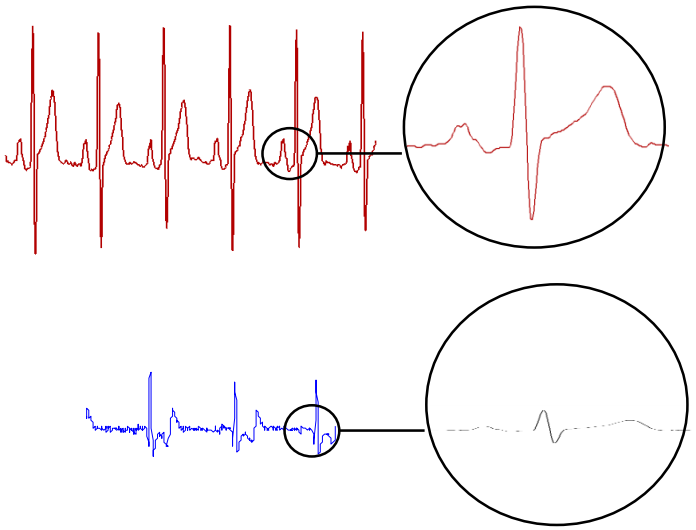
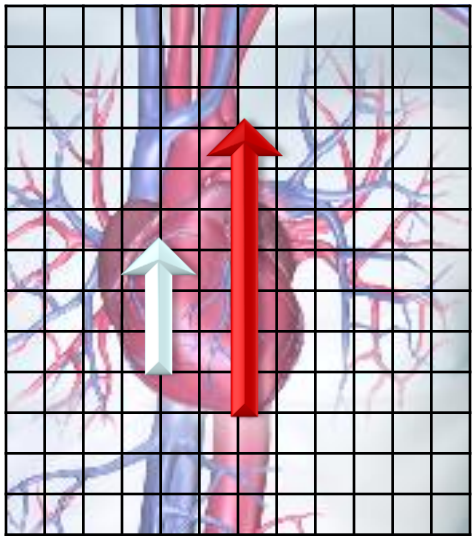
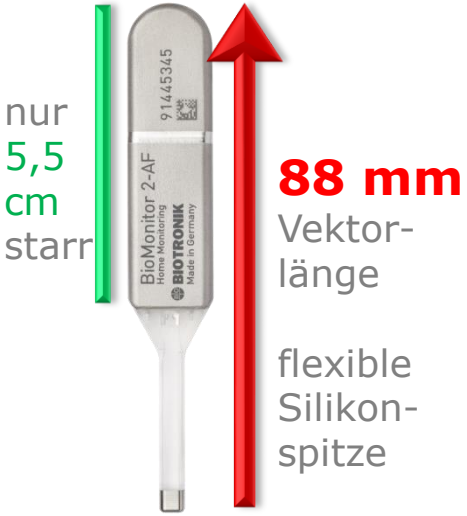
- Präzise Arrhythmiediagnostik mittels optimierter Signalqualität

- Ein längerer Wahrnehmungsvektor kann aufgrund der höheren Potentialdifferenz zu einer größeren Signalamplitude und einem günstigeren Signal-Rausch-Verhältnis führen.

Geben Sie hier eine Formel ein.







4 ccm Volumen

EGM Representative of AT/AF Due to Far-Field R-Wave Sensing

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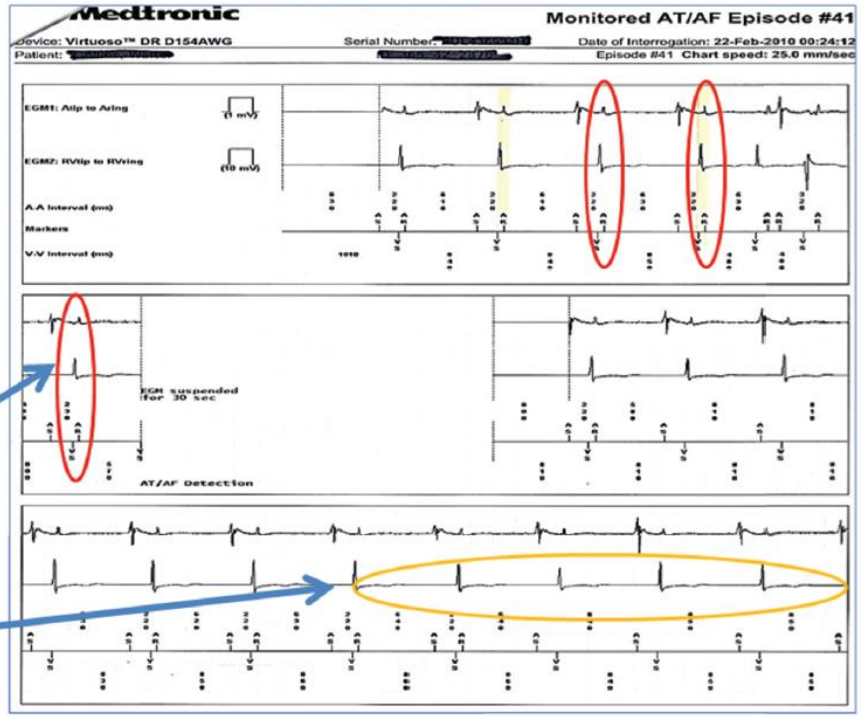

Intracardiac electrogram (EGM) demonstrating sensing of the R-wave on the atrial lead, resulting in false detection of atrial tachycardia (AT)/atrial fibrillation (AF). AR = atrial refractory event.

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

Implantable Cardiac Monitor Strips Exemplifying True and False AT/AF

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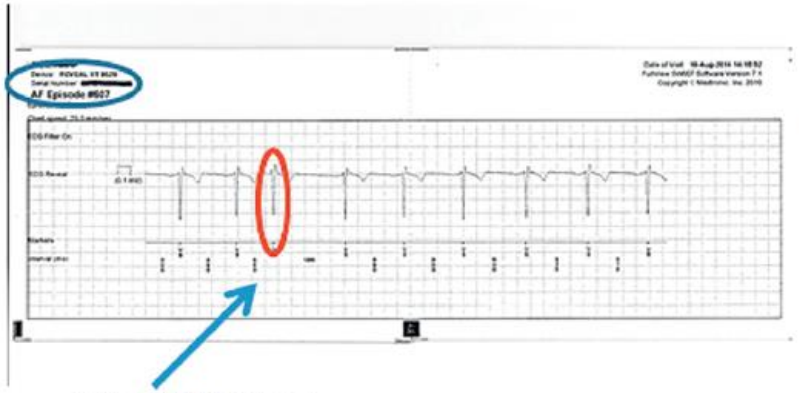
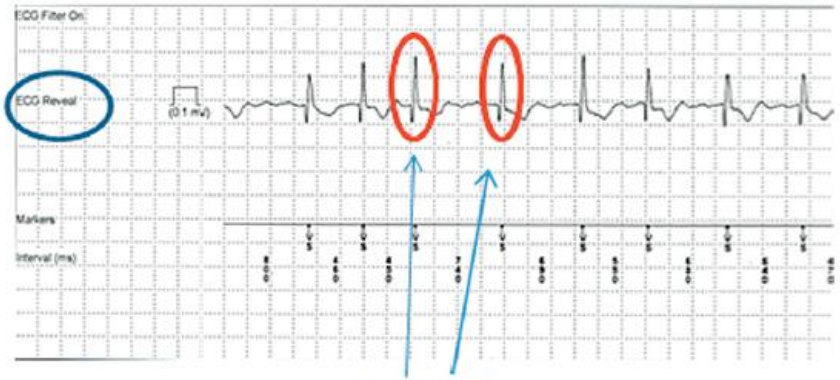
False AT/AF



False AT/AF triggered due to PVC

True AT/AF



Note: irregular R-R intervals.

Examples of true and false detection of atrial tachycardia (AT)/atrial fibrillation (AF) by implantable cardiac monitors. False AT/AF detection due to irregular R-R intervals in a patient with frequent premature ventricular contractions (PVC).

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

CRYSTAL AF

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cryptogenic Stroke and Underlying Atrial Fibrillation

Tommaso Sanna, M.D., Hans-Christoph Diener, M.D., Ph.D., Rod S. Passman, M.D., M.S.C.E., Vincenzo Di Lazzaro, M.D., Richard A. Bernstein, M.D., Ph.D., Carlos A. Morillo, M.D., Marilyn Mollman Rymer, M.D., Vincent Thijs, M.D., Ph.D., Tyson Rogers, M.S., Frank Beckers, Ph.D., Kate Lindborg, Ph.D., and Johannes Brachmann, M.D., for the CRYSTAL AF Investigators*

T. Sanna, ... J. Brachmann N Engl J Med;370:2478-86, 2014.

Patient Flow in der CRYSTAL-AF Studie

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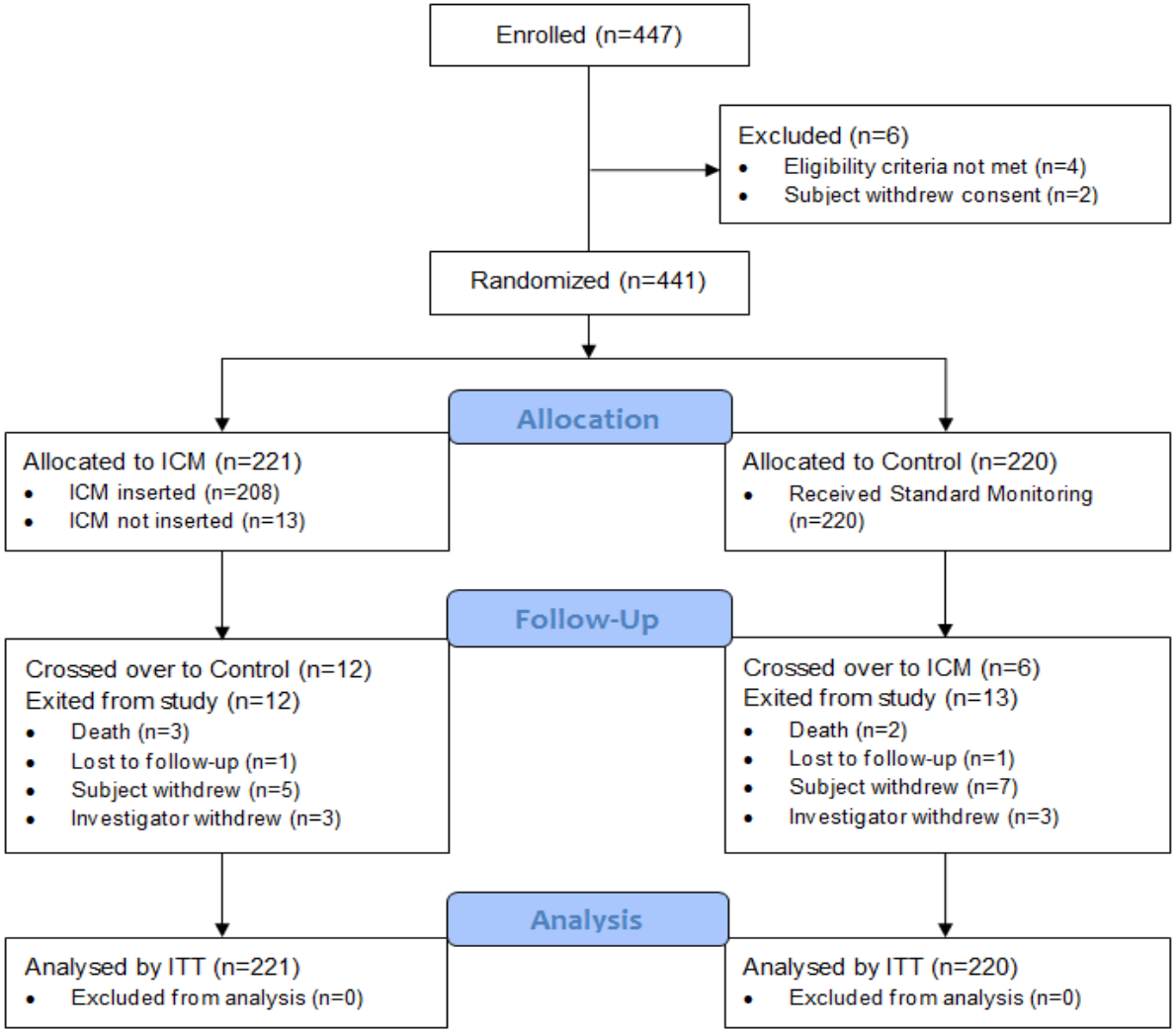

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Methods

AF defined as an episode of irregular heart rhythm, without detectable p waves, greater than 30 seconds

AF episodes were identified by patient's physician and adjudicated by an independent committee

Detektion von Vorhofflimmern nach kryptogenem Schlaganfall mittels implantierbarem Ereignisrekorder

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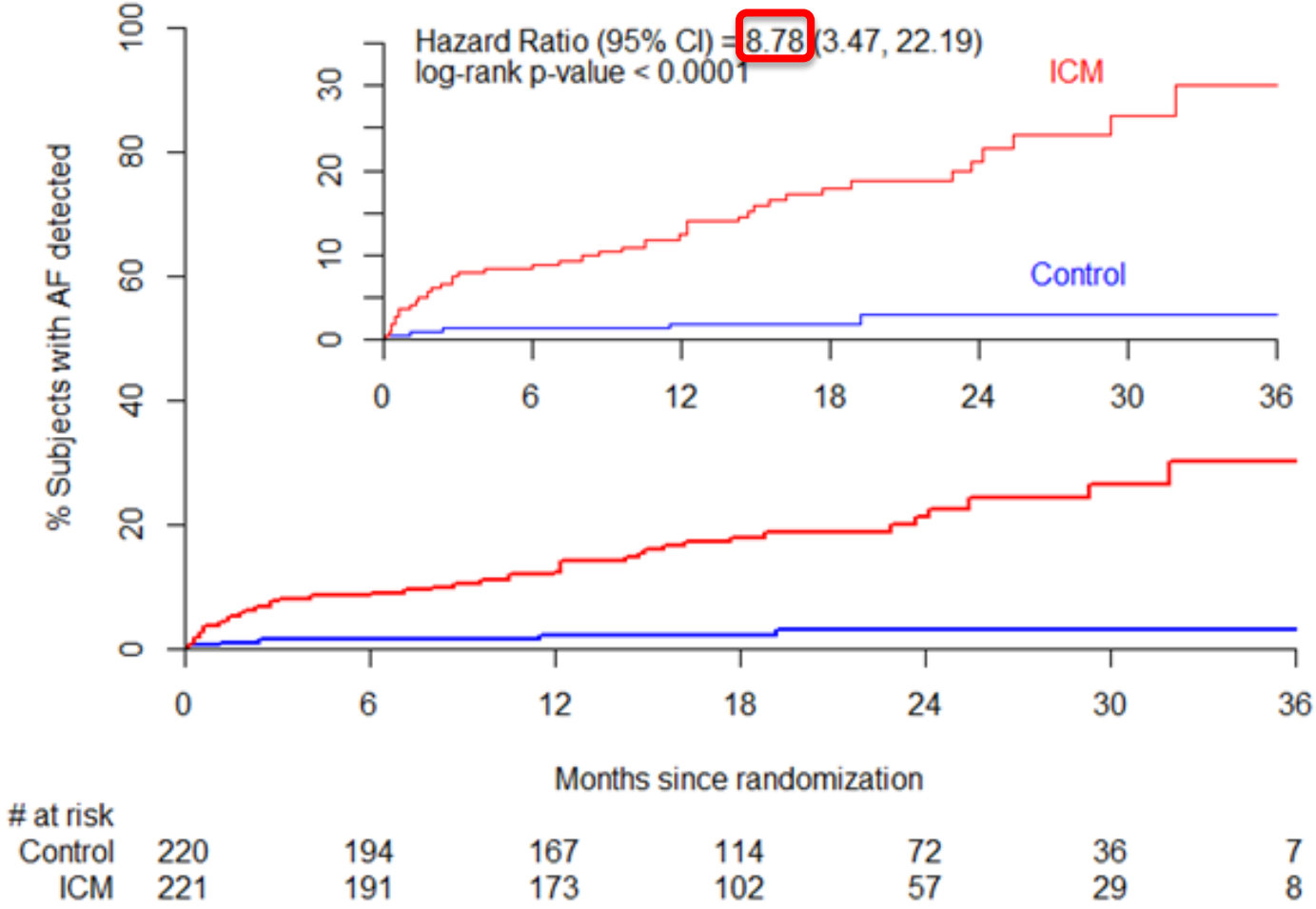

T. Sanna…J.Brachmann; N Engl J Med;370:2478-86, 2014

Primary Endpoint CRYSTAL-AF Study: Detection of AF at 6 months

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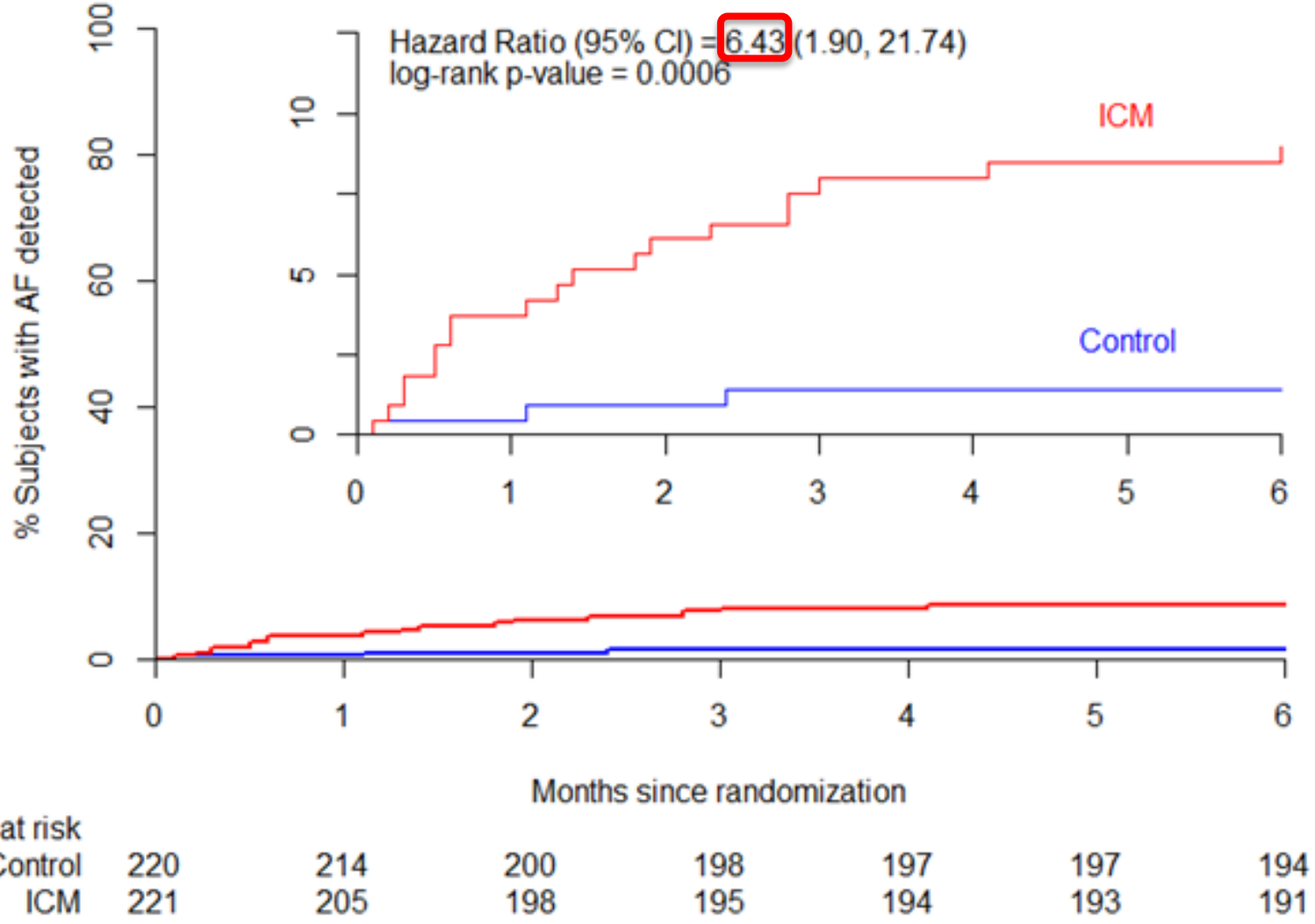

Sanna, ..Brachmann et al NEJM 2014

Rate of detection in ICM arm was 8.9% vs 1.4% in control arm

Atrial Fibrillation Duration in ICM Arm at 12 months (N=29)

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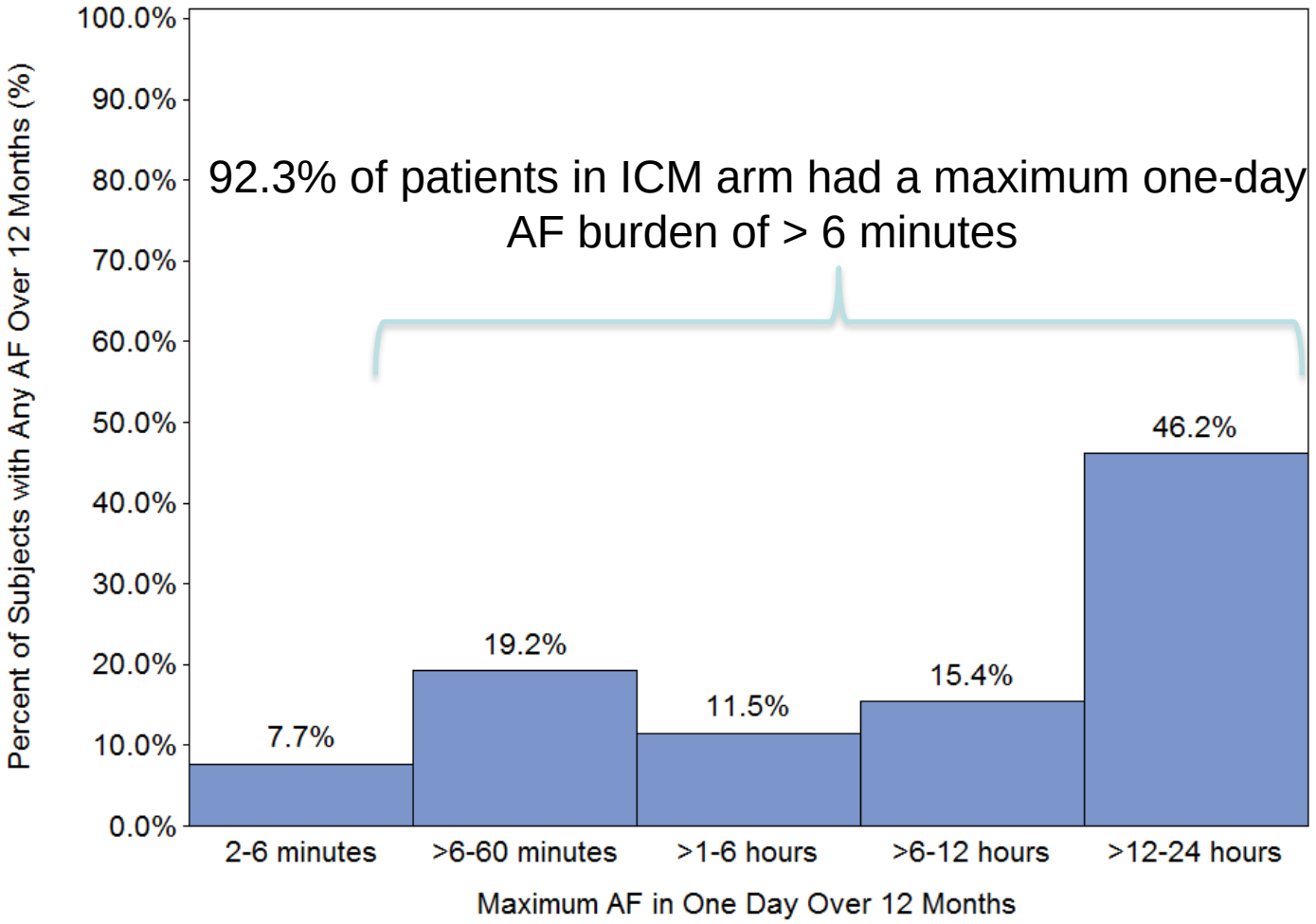

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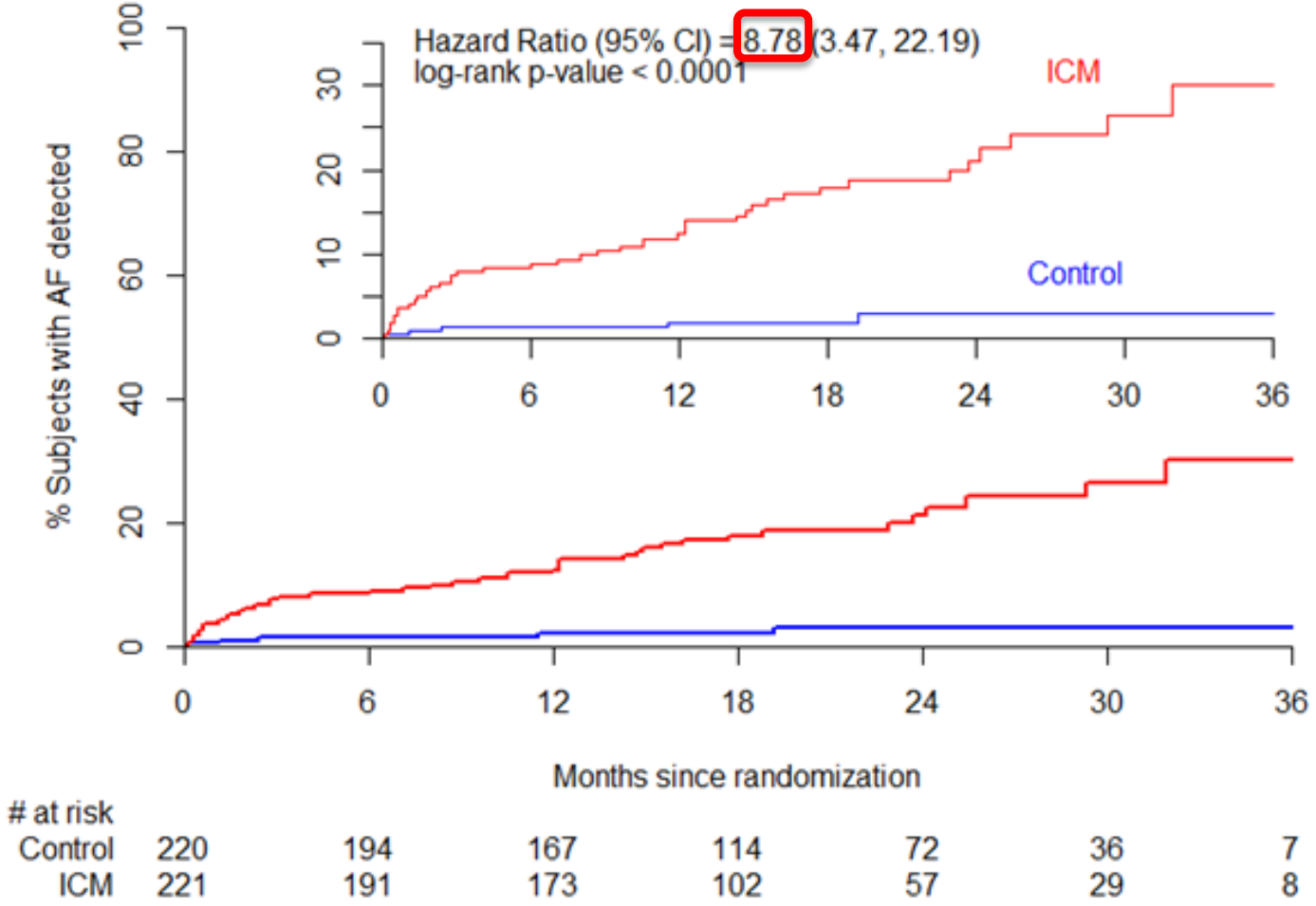
Detektion von AF nach 3 Jahren

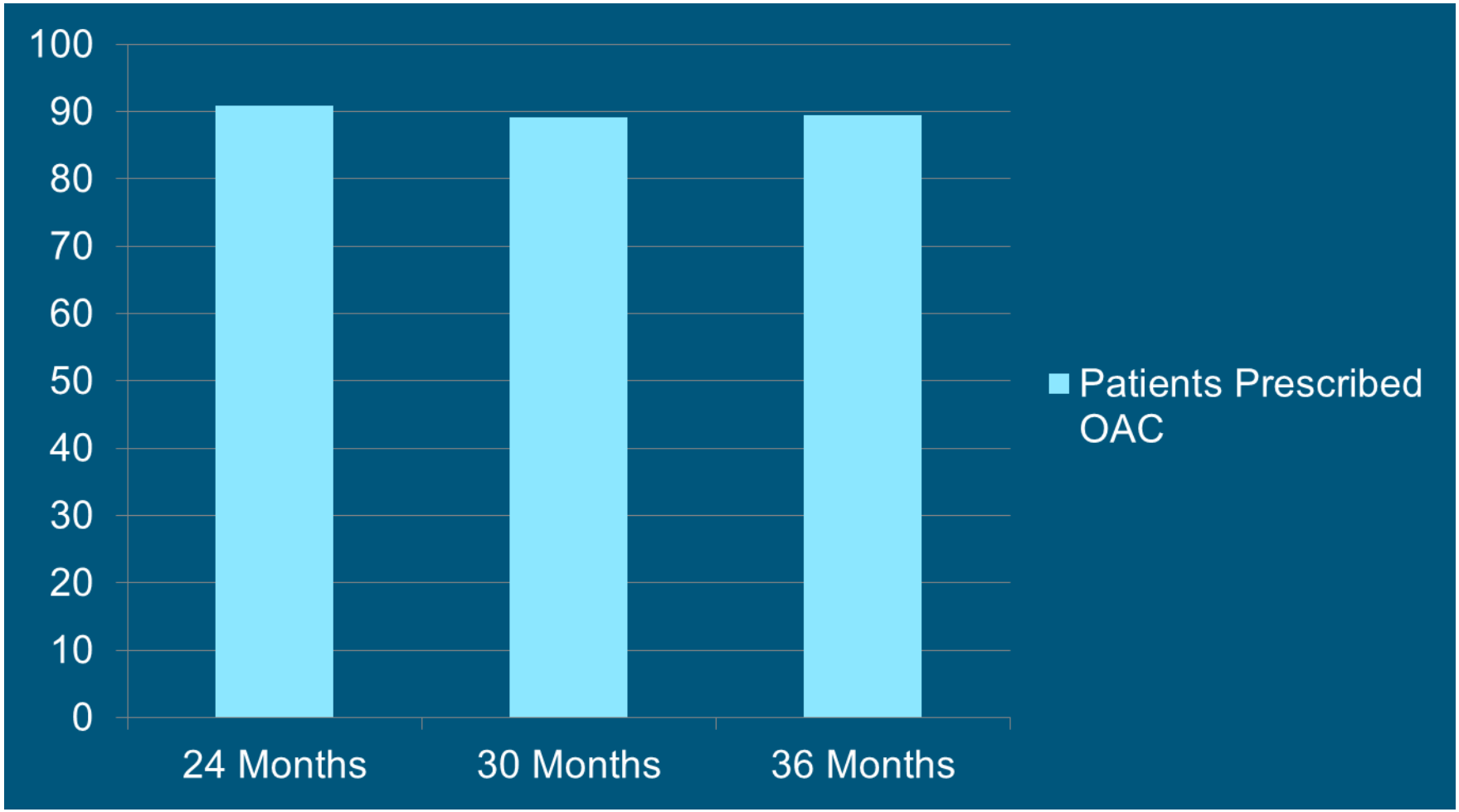


Brachmann et al Circ AE 2016

Rate of detection in ICM arm was 30.0% vs 3.0% in control arm

Clinical Decisions

OAC Usage in AF Patients: Both Arms



Approximately 90% of patients with AF were prescribed OAC

Brachmann et al Circ AE 2016

Metaanalysis of Outpatient Monitoring in Patients with Cryptogenic Stroke

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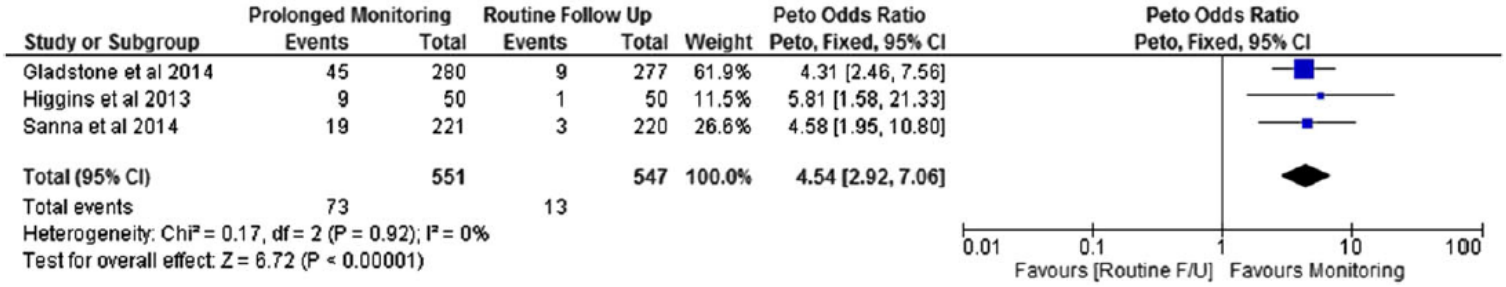
Table III.

Quality Assessment Scale for the Randomized Controlled Trials Included in the Meta-analysis

	Selection			Performance	Detection	Attrition	
	Was Allocation Adequate?*	Was an Adequate Method of Randomization Described?	Were Groups Similar at the Start of the Study?	Were the Patients/ Caregivers Blinded to to the Inter-vention?	Was the Outcome Ascertained Blindly?	What Percent was Lost to Follow-Up?	Were All Patients Analyzed in the Group to Which They Assigned?
Gladstone et al. 2014	Y	Y	Y	N	N	2.27%	Y
Higgins et al. 2013	Y	N	Y	N	N	0	Y
Sanna et al. 2014	Y	Y	Y	N	N	0.45%	Y

*"Adequate" means the use of central site, numeric code, opaque envelopes, and other appropriate procedures as described by Juni et al.



Afzal et al; PACE; 38:1236–1245, 2015

Detection of AF by ILR compared to Wearable Monitors in Patients with Cryptogenic Stroke

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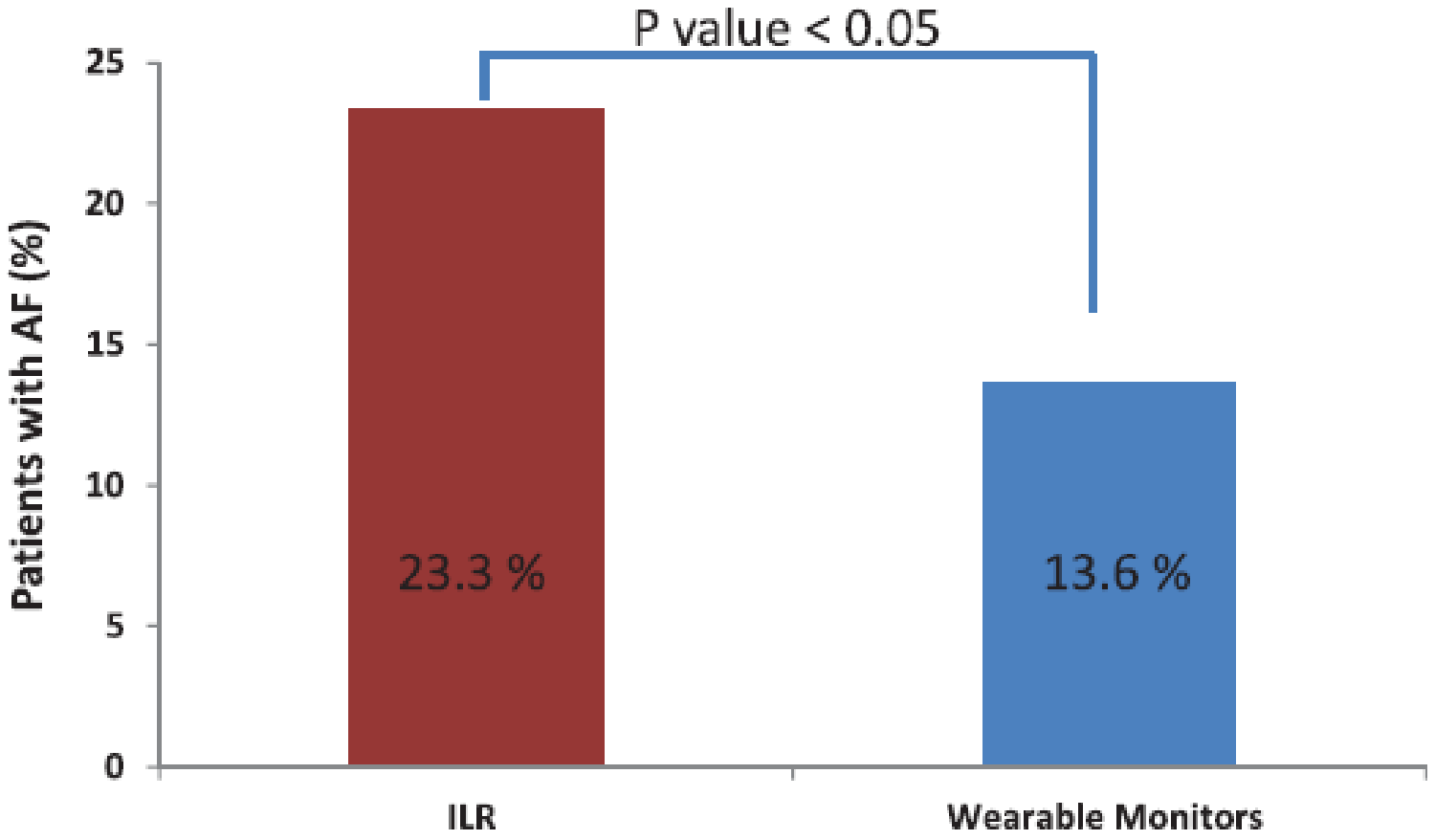

Afzal et al; PACE; 38:1236–1245, 2015

Comparison of Risk Factors between Patients with or without AF during Prolonged Monitoring

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	Mean ± SD		
Risk Factor	Patients with AF	Patients Without AF	P Value
Age (years)	67.5 ± 4 (106)	59.5 ±6 (580)	0.01
Hypertension (%)	63.7 ± 11 (132)	60.9 ± 19.6 (653)	0.72
Diabetes mellitus (%)	17.3 ± 11.8 (127)	15.3 ± 11 (576)	0.72

Afzal et al; PACE; 38:1236–1245, 2015

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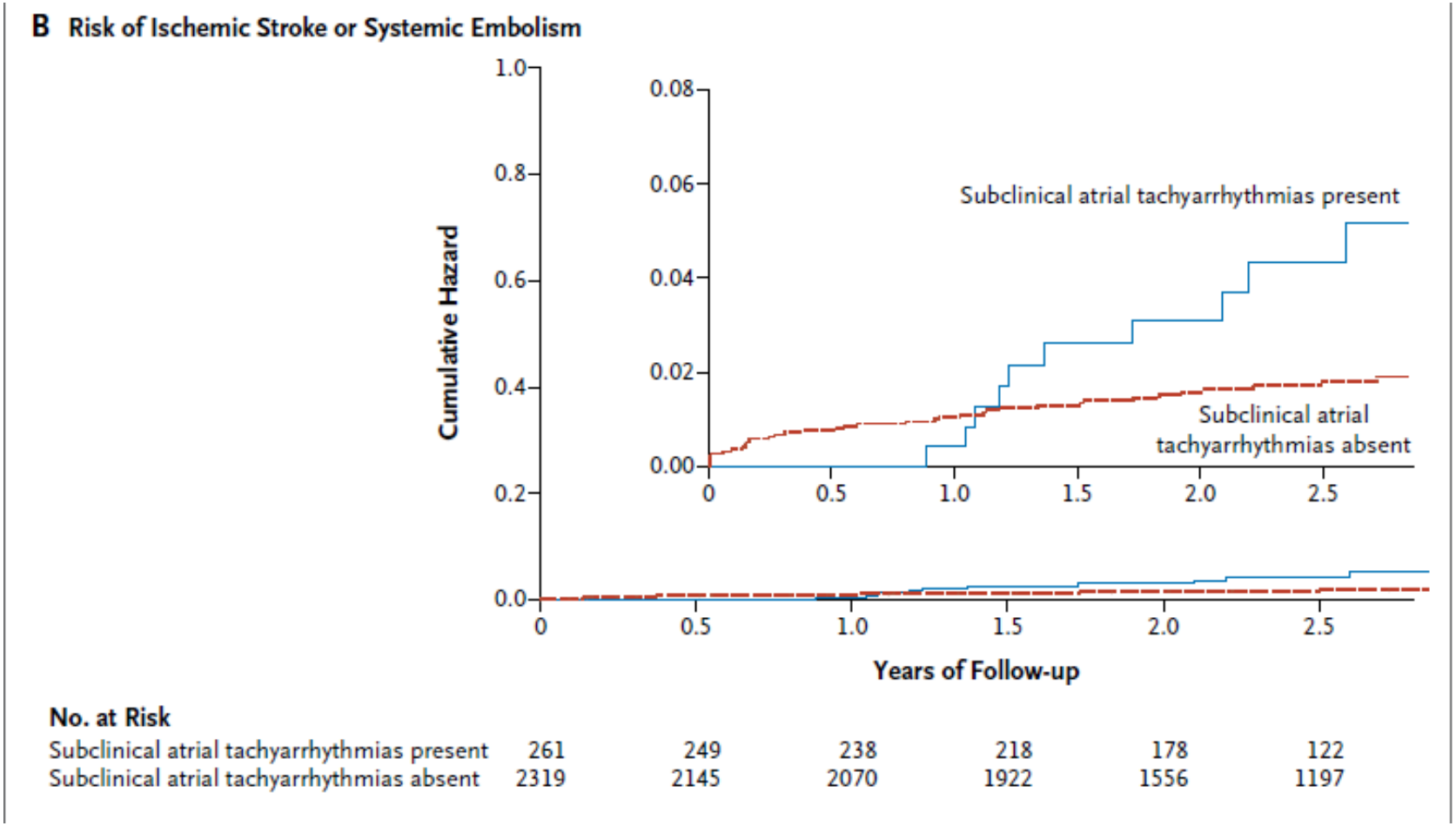
ASSERT-Studie
Significance of Asymptomatic Episodes of AF



Healey et al; N Engl J Med;366:120-9, 2012

European Heart Journal (2014) **35**, 508–516
doi:10.1093/eurheartj/eht491

CLINICAL RESEARCH
Atrial fibrillation

Device-detected atrial fibrillation and risk for stroke: an analysis of >10 000 patients from the SOS AF project (Stroke preventiOn Strategies based on Atrial Fibrillation information from implanted devices)

Giuseppe Boriani[1]*, Taya V. Glotzer[2], Massimo Santini[3], Teena M. West[4], Mirko De Melis[4], Milan Sepsi[5], Maurizio Gasparini[6], Thorsten Lewalter[7], John A. Camm[8], and Daniel E. Singer[9]

[1]Department of Experimental, Diagnostic and Specialty Medicine, Institute of Cardiology, University of Bologna, S.Orsola-Malpighi University Hospital, Via Massarenti 9, Bologna 40138, Italy; [2]Hackensack University Medical Center, Hackensack, NJ, USA; [3]Cardiology Department, San Filippo Neri Hospital, Rome, Italy; [4]Medtronic Bakken Research Center, Maastricht, The Netherlands; [5]Department of Internal Medicine – Cardiology, University Hospital Brno, Brno, Czech Republic; [6]Department of Cardiology, Humanitas Clinical and Research Center, Rozzano-Milano, Italy; [7]Isar Heart Center Munich, Munich, Germany; [8]Cardiac and Vascular Sciences, St George's Hospital Medical School, London, UK; and [9]General Medicine Division, Massachusetts General Hospital, and Harvard Medical School, Boston, MA, USA

Received 22 March 2013; revised 26 September 2013; accepted 7 November 2013; online publish-ahead-of-print 11 December 2013

Boriani et al; European Heart Journal;35:508–516, 2014

Baseline characteristics by study

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	Total (n = 10 016)	PANORAMA (n = 3556)	TRENDS (n = 2553)	ClinicalService (n = 3907)
Age, median years (IQR)	70 (61, 76)	69 (60, 76)	73 (64, 79)	68 (60, 74)
Male, *n* (%)	6859 (69)	2096 (59)	1694 (66)	3069 (79)
Diabetes mellitus, *n* (%)	2537 (25)	896 (25)	817 (32)	824 (21)
Hypertension, *n* (%)	5896 (59)	2116 (60)	1940 (76)	1840 (47)
Atrial fibrillation, *n* (%)				
Paroxysmal	1923 (19)	784 (22)	678 (27)	461 (12)
Persistent	478 (5)	91 (3)	48 (2)	339 (9)
Oral anticoagulation, *n* (%)	1822 (18)	631 (18)	526 (21)	665 (17)
$CHADS_2$ group, *n* (%)				
$CHADS_2$ 0–1	4133 (41)	1684 (47)	722 (28)	1727 (44)
$CHADS_2$ 2–6	5883 (59)	1872 (53)	1831 (72)	2180 (56)
Prior stroke, *n* (%)	589 (6)	89 (3)	345 (14)	155 (4)
Device type				
PM	4277 (43)	2726 (77)	1238 (49)	313 (8)
ICD	2004 (20)	404 (11)	822 (32)	778 (20)
CRT	3735 (37)	426 (12)	493 (19)	2816 (72)

Boriani et al; European Heart Journal;35:508–516, 2014

Zeitabhänige Detektion von Vorhofflimmern mit einer Dauer von mindestens 5 Minuten

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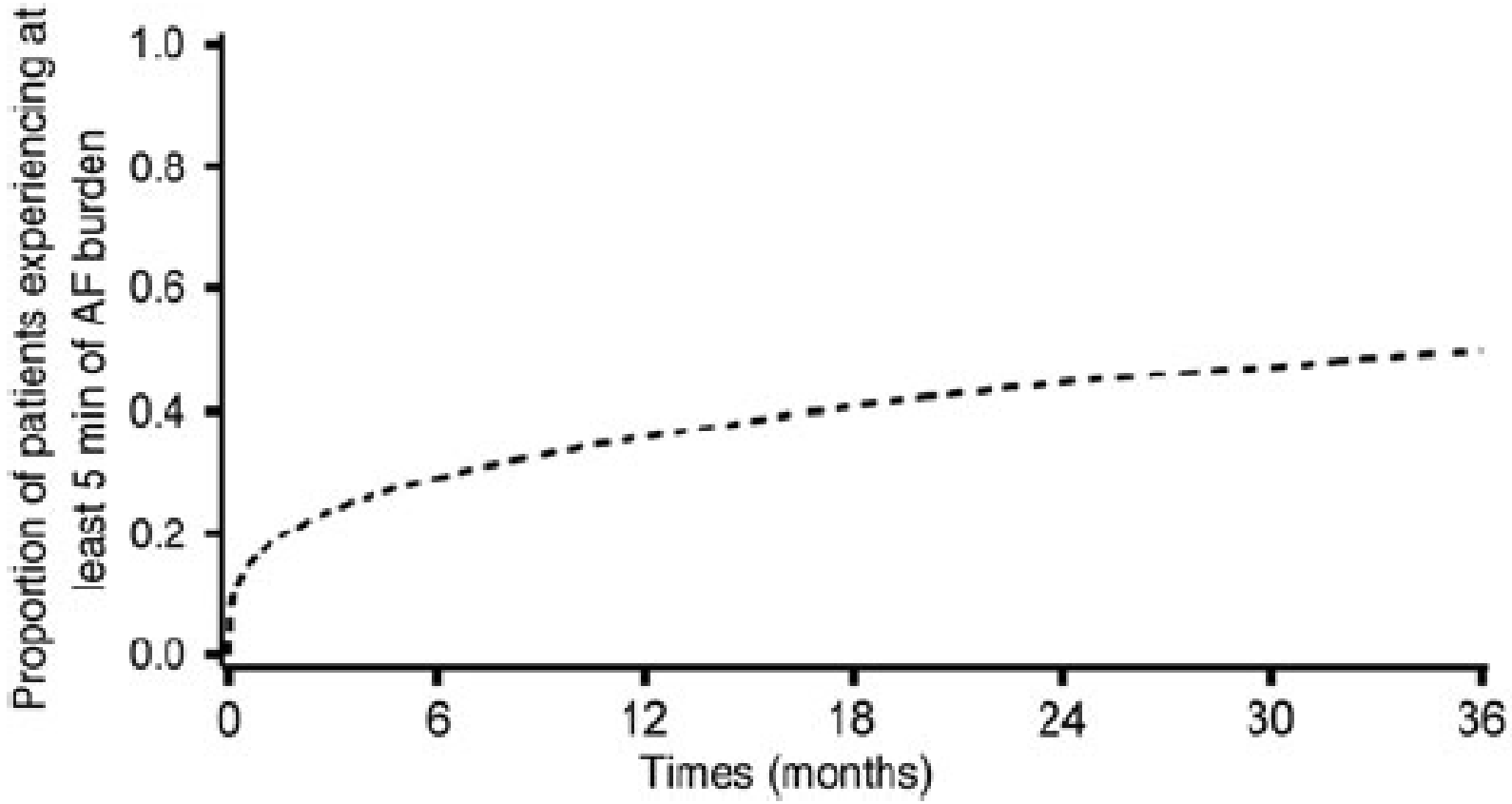

Boriani et al; European Heart Journal;35:508–516, 2014

Kumulativer zeitabhängiger Anteil von Patienten mit Detektion von mindestens 1 Stunde Vorhofflimmern

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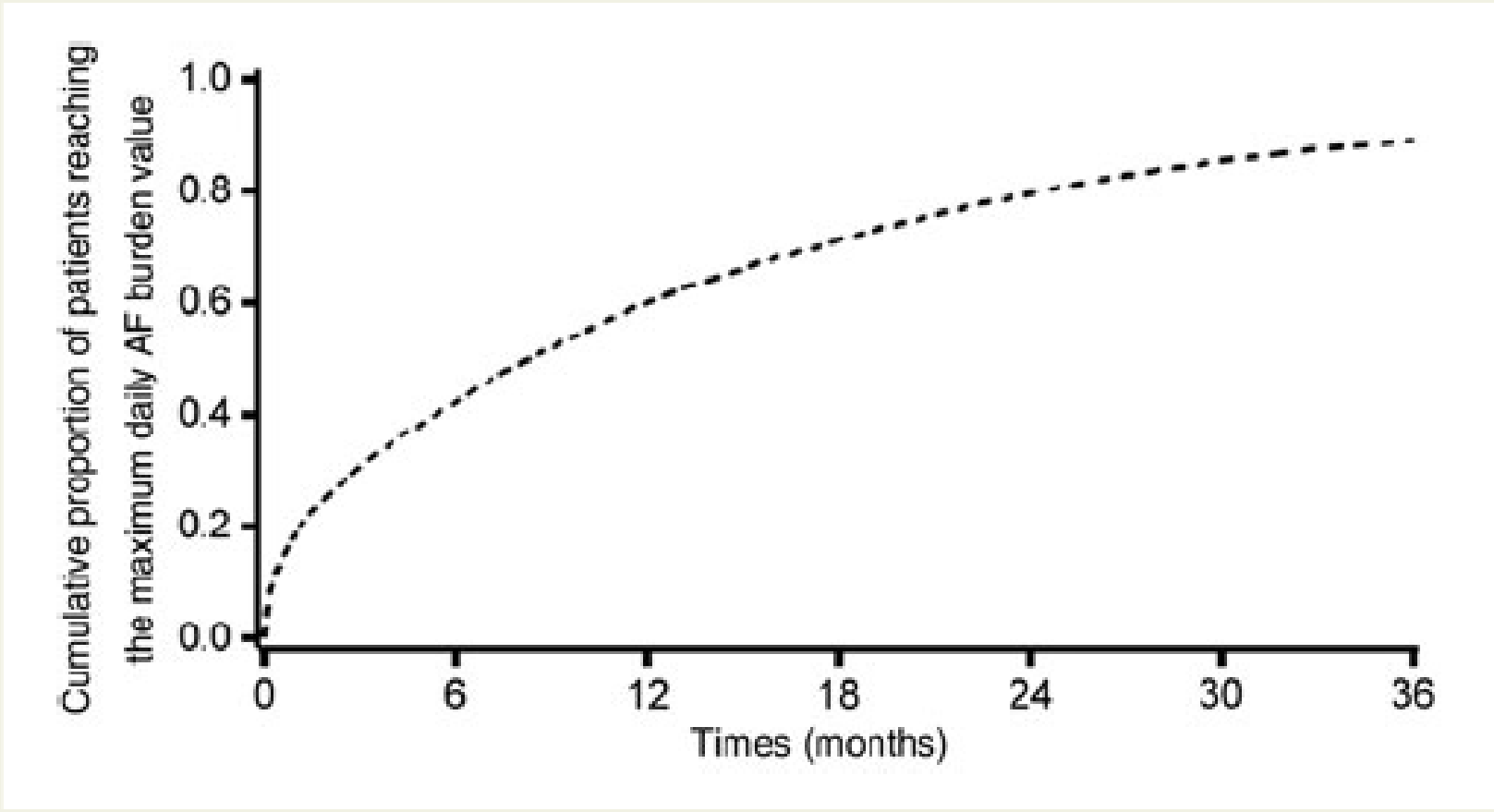

Boriani et al; European Heart Journal;35:508–516, 2014

Verteilung der Patienten nach Dauer der Vorhofflimmerlast und cerebrales Ischämierisiko

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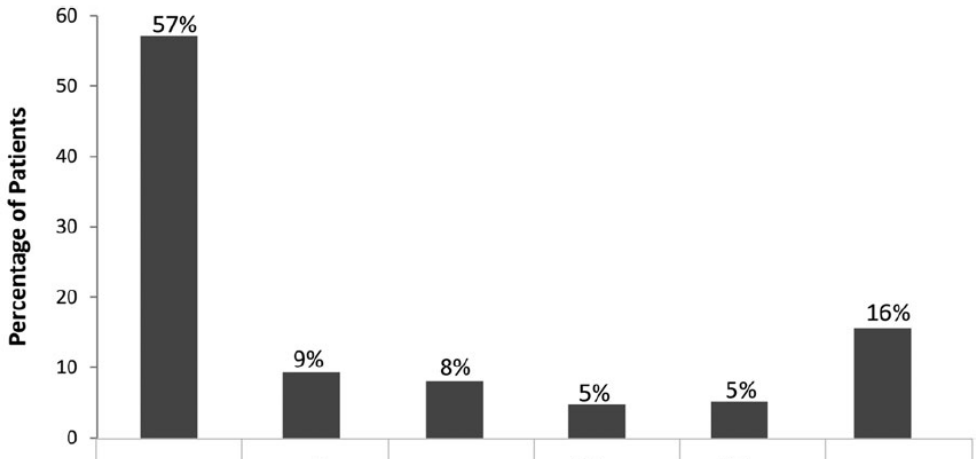

	0 to <5 minutes of AF burden	≥5 minutes to <1 hour AF burden	≥1 hour to <6 hours AF burden	≥6 hours to <12 hours AF burden	≥12 hours to <23 hours AF burden	≥23 hours AF burden
Median Follow Up, months	21	27	26	26	27	28
Person years	12966	2491	2077	1171	1375	4314
Stroke events, n(%)	31 (0.54%)	2 (0.21%)	7 (0.86%)	3 (0.65%)	4 (0.77%)	10 (0.64%)
Stroke rate, % per year	0.24%	0.08%	0.34%	0.26%	0.30%	0.23%
Stroke or TIA events, n(%)	41 (0.72%)	8 (0.86%)	14 (1.72%)	5 (1.08%)	6 (1.15%)	25 (1.61%)
Stroke or TIA rate, % per year	0.32%	0.32%	0.67%	0.43%	0.44%	0.49%

Boriani et al; European Heart Journal;35:508–516, 2014

Patienten ohne OAK am Studienbeginn adjustiert für den $CHADS_2$ score

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	Total	Events	HR for AF burden ≥1 h vs. <1 h (95% CI)	*P*-value
Stroke	8122	44	2.09 (1.10, 3.96)	0.0239
Stroke + TIA	8122	69	2.05 (1.24, 3.39)	0.0051
Adjusting for $CHADS_2$ score				
Stroke	8122	44	1.90 (1.00, 3.61)	0.0487
Stroke + TIA	8122	69	1.89 (1.14, 3.12)	0.0135

Boriani et al; European Heart Journal;35:508–516, 2014

$CHADS_2$ and Associated Stroke Risk in the NRAF and ASSERT Trials

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	NRAF			ASSERT		
	n = 1,733	Number of CVAs (94)	Adjusted Stroke Risk	n = 259	Number of CVAs (11)	Adjusted Stroke Risk
$CHADS_2 = 0$	120	2	1.9 (1.2-3.0)	–	–	–
$CHADS_2 = 1$	463	17	2.8 (2-3.8)	68	1	2.11 (0.23-18.9)
$CHADS_2 = 2$	523	23	4.0 (3.1-5.1)	119	4	1.83 (0.62-5.4)

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

Comparison of Patient Characteristics Between NRAF and ASSERT Trials

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	NRAF (N = 1,733)	ASSERT (N = 261 [With Subclinical AT])	Comparison of Proportions (p Value)
Age, yrs	81	77 ± 7	
CHF	56%	14.9%	<0.0001
HTN	56%	–	
Male	42%	56.3%	<0.0001
Female	58%	43.7%	<0.0001
DM	23%	22.6%	0.9487
Prior CVA or TIA	25%	11.9%	<0.0001
ASA therapy	31%	61.3%	<0.0001
Mean $CHADS_2$ score	2.1 (without aspirin) 2.3 (with aspirin)	2.2 ± 1.1	0.1711

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

Early detection of occult atrial fibrillation and stroke prevention

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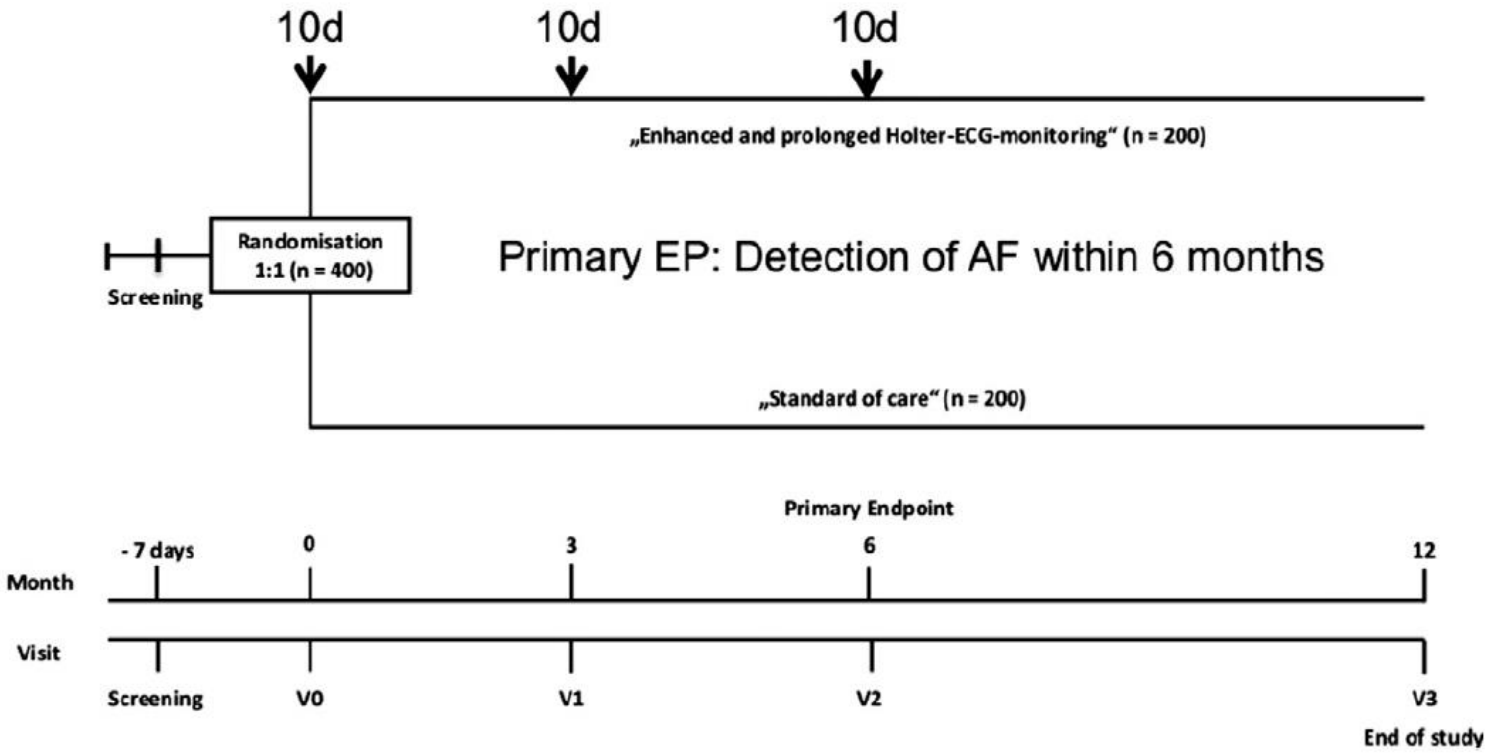
Find-AF Study



Study design flowchart.

Weber-Krüger et al; Am Heart J 2014;168:438-45

Find-AF Study

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Inclusion criteria

1. Recent cerebral ischemia defined as stroke (sudden focal neurologic deficit lasting >24 h consistent with the territory of a major cerebral artery and categorized as ischemic) *and/or* a corresponding lesion on brain imaging
2. Stroke symptoms started ≤7 d ago
3. Age ≥60 y
4. mRS ≤2 (prior to index event)

Exclusion criteria

1. History of AF/flutter or documented AF/flutter prior to randomization
2. Indication for oral anticoagulation at randomization
3. Absolute contraindication for oral anticoagulation at randomization
4. Intracerebral bleeding in medical history
5. Patient scheduled for Holter ECG or cardiac event-recording monitoring ≥48 h
6. Carotid artery stenosis of >50% (NASCET) needing revascularization and ipsilateral to ischemic territory
7. Implanted pacemaker device or cardioverter/defibrillator
8. Life expectancy <1 y for reasons other than stroke (eg, metastatic cancer disease)
9. Concomitant participation in another randomized controlled trial

Weber-Krüger et al; Am Heart J 2014;168:438-45

Summary of ongoing trials investigating the safety/efficacy of OAC treatment of occult AF

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	Population	Intervention	Primary outcomes	Impact on current understanding
ARTESiA	CHA2DS2-VASc ≥4 with at least a single AHRE ≥175 bpm lasting ≥6 min detected by ILR or intracardiac device *No history or ECG evidence of clinical AF*	Randomised to either aspirin 81 mg daily (control) or apixaban 5 mg twice daily (intervention)	Incidence of stroke and major bleeding events	Will be the first trial directly investigating the risk/benefit of OAC treatment in the device-detected AHRE population.
STROKESTOP	All persons aged 75 years and 76 years in two Swedish provinces *No history of AF*	Twice-daily ECG screening+OAC treatment if AF detected (single episode duration >30 s, or 2 or more episodes >10 s)	Incidence of stroke and major bleeding events	Will be the first trial investigating population-based screening for occult AF and the effect on stroke prevention

	Population	Intervention	Primary outcomes	Impact on current understanding
REVEAL-AF	CHADS2 ≥3, or ≥2 +CAD, CKD, OSA or COPD *No history of AF*	Insertion of ILR	AF episode >6 min, thromboembolism	Will further understanding of risk factors for occult AF, ILR for detection of AF >6 min, temporal relationship between AF episode and stroke
ASSERT-II	Age ≥65 +CHA2DS2-VASc ≥2 +LA enlargement or elevated p-BNP *No history of AF*	Insertion of ILR	AF episode >5 min, thromboembolism	Will further understanding of risk factors for occult AF, ILR for detection of AF >5 min, temporal relationship between AF episode and stroke

	Population	Intervention	Primary outcomes	Impact on current understanding
REACT COM	CHADS2 of 1 or 2, recently implanted Medtronic REVEAL XT loop recorder No permanent AF or recent AF episode lasting >1 h	Rapid initiation of 30 days of NOAC therapy following a remotely detected episode of AF	OAC utilisation, incidence of stroke, death and major bleeding events	Will demonstrate safety/efficacy of treating paroxysmal or persistent AF with NOAC only during times temporally related to AF episodes (other studies have demonstrated a weak temporal relationship between episodes of AF and stroke)
TACTIC-AF	History of paroxysmal or persistent AF currently taking NOAC+intracardiac device (St Jude) No permanent AF	Withdrawal/reinitiation of NOAC based on remote-monitoring of atrial activity (AT/AF)	Incidence of stroke, death, cardiovascular complications	Will demonstrate the safety of OAC cessation in patients with low AF burden, temporal relationship between stroke and AF, effect of weekly remote device interrogation

2,2015

AT/AF Burden Per Day Relative to Onset of Strokes/TIA/SE From the ASSERT and TRENDS Studies

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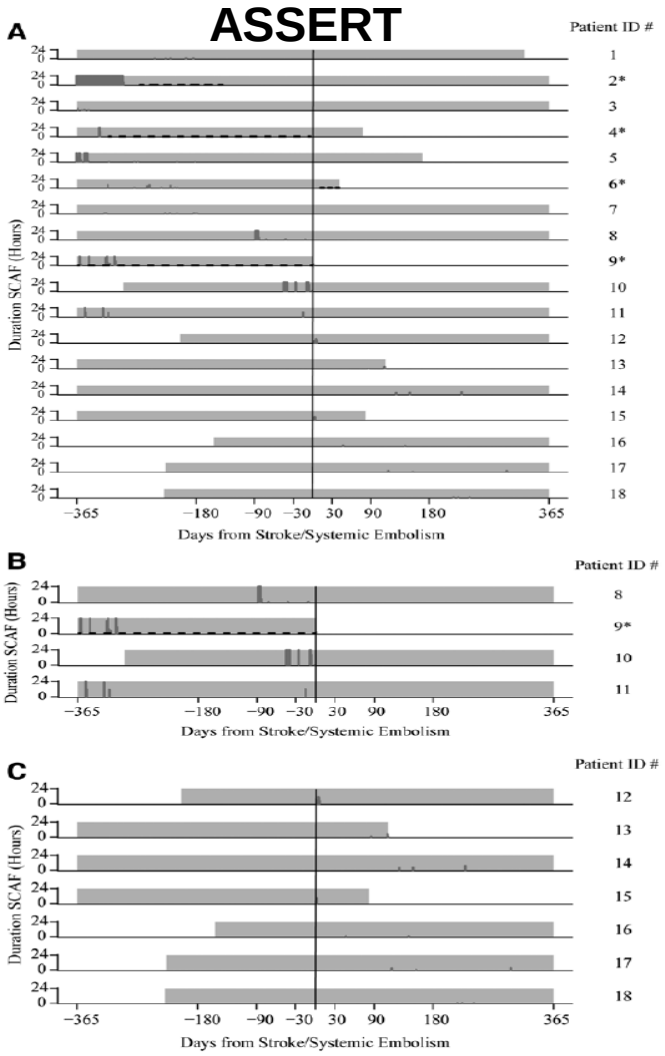

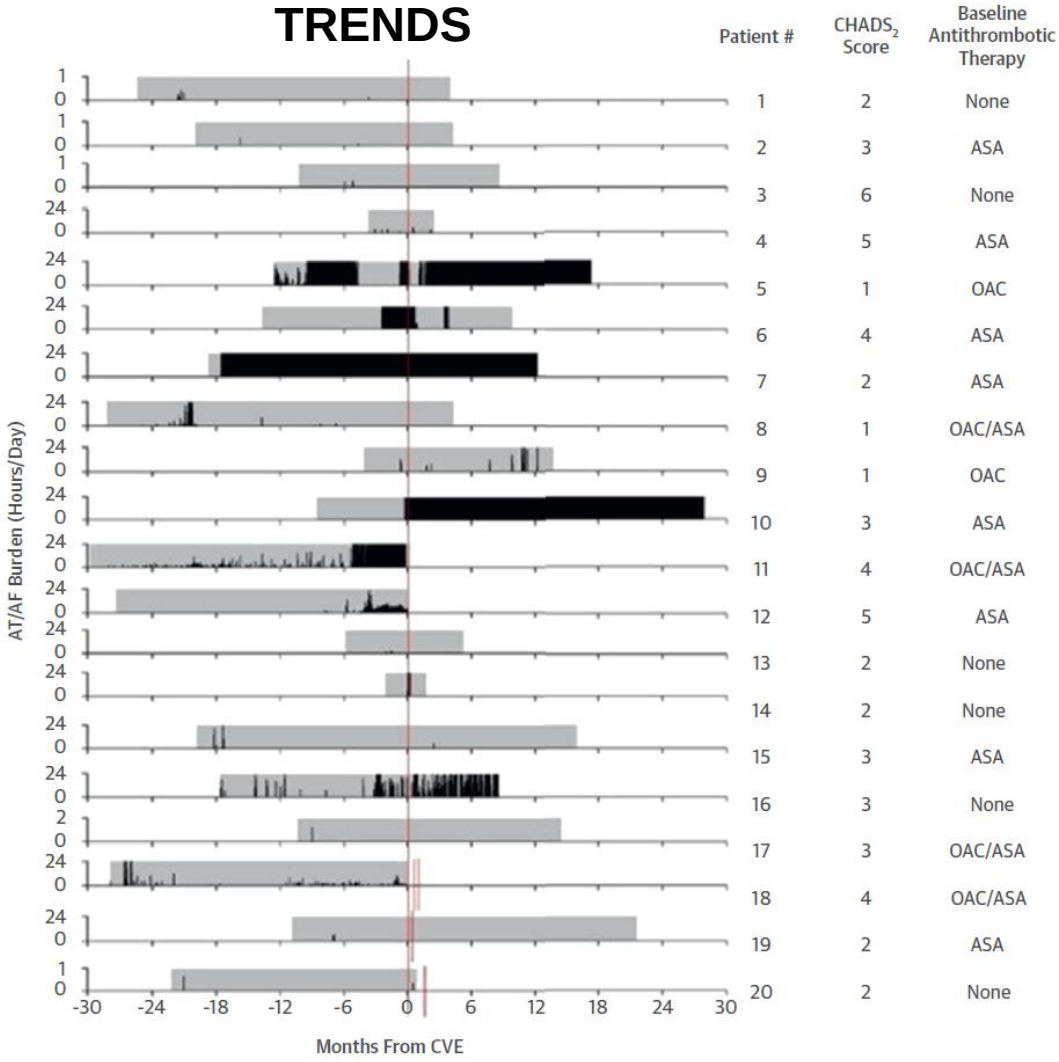

Chen-Scarabelli et al; J Am Coll Cardiol;65:281–94,2015

AF-Induced Remodeling

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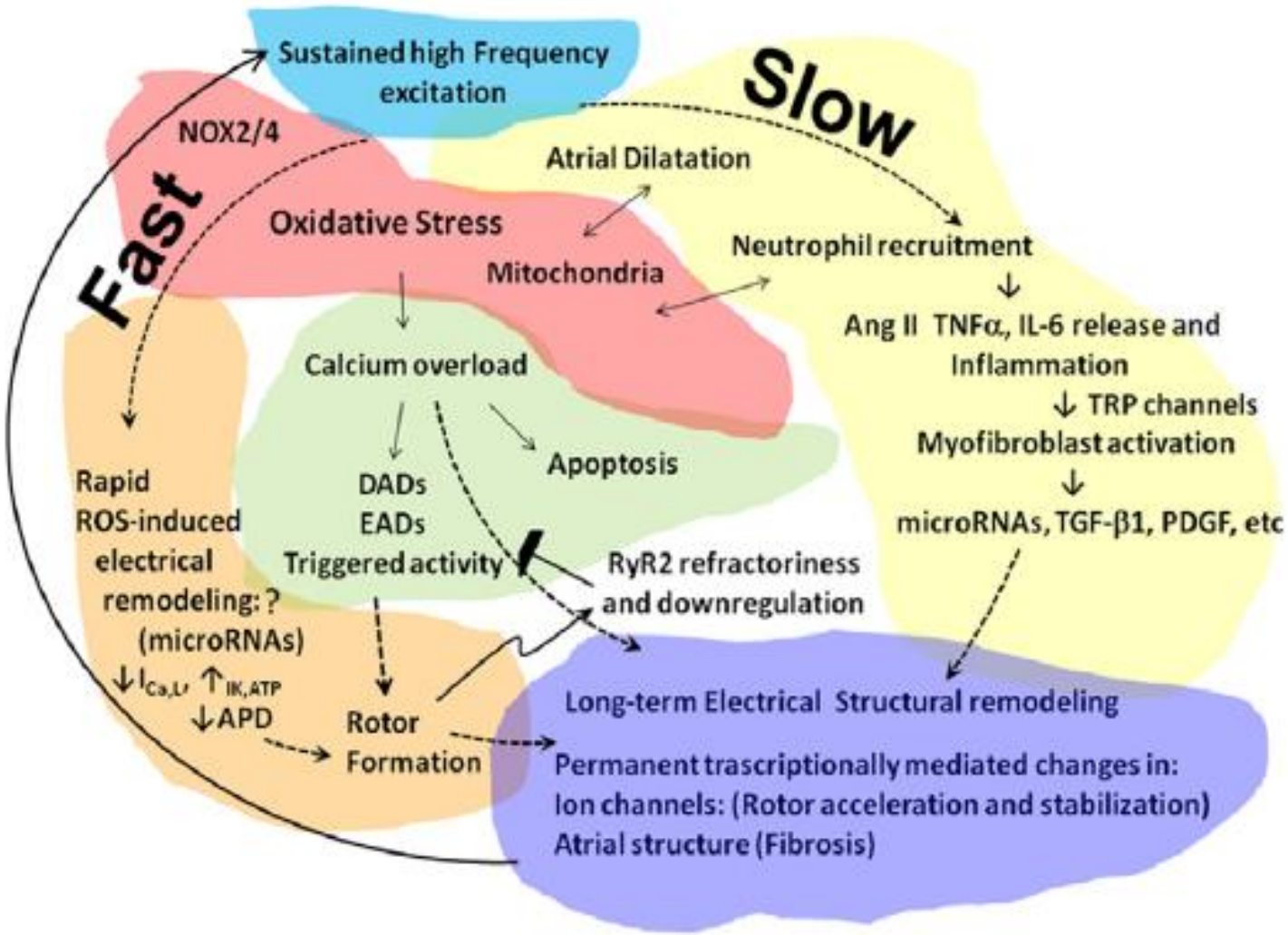

Jalife et al; Trends in Cardiovascular Medicine; 2015

Myofibroblasts Induce Structural Remodeling of Cardiomyocytes

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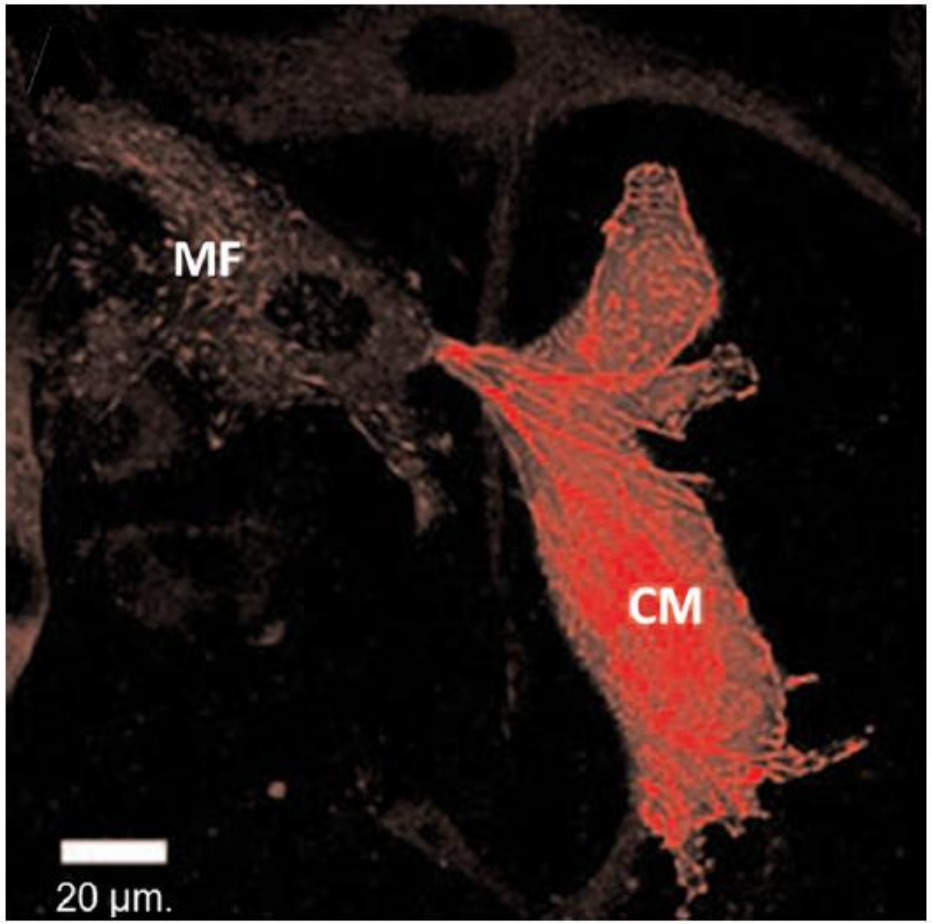

Protein organization at the myofibroblast (MF)-cardiomyocyte (CM) resulting in vinculin reorganization parallel to the direction of the strain induced by the MF

Jalife et al; Trends in Cardiovascular Medicine; 2015

Detektion von linksatrialer Fibrose mittels Gadolinium DE-MRT

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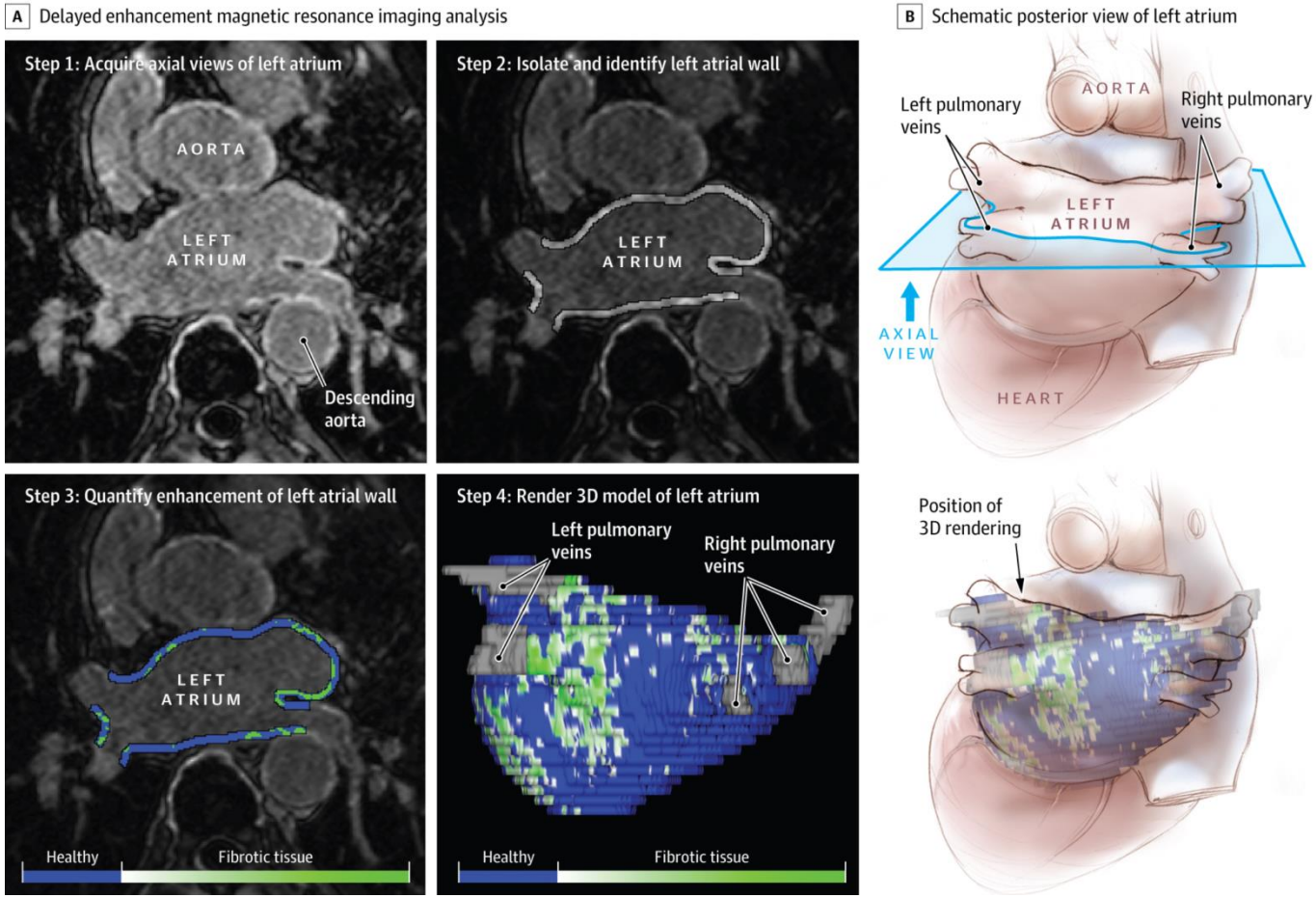

Marrouche, .. Brachmann JAMA. 2014 Feb 5;311(5):498-506

Left Atrial Struktural Remodeling (Fibrosis) by DE-MRT and Risk of Stroke in Patients with AF

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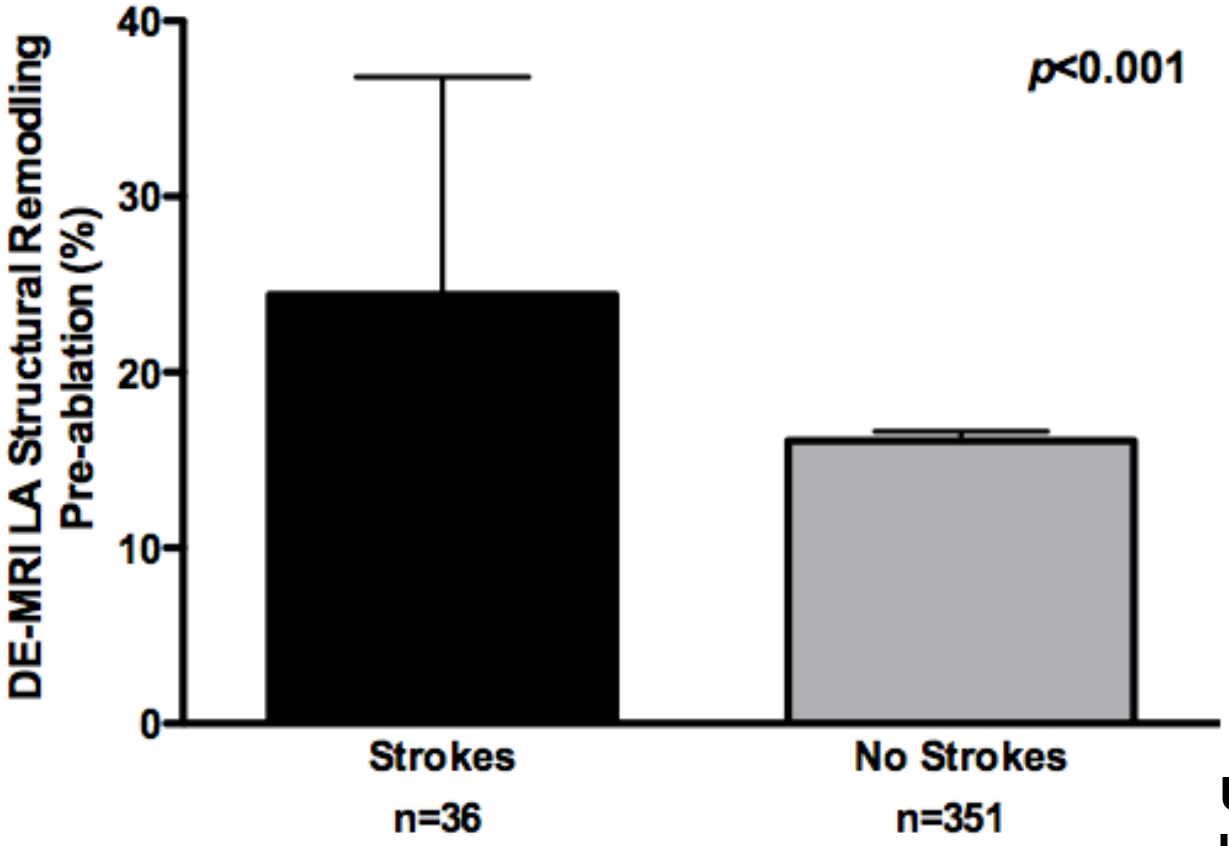

Univ of Utah and Klinikum Coburg

Dacarrett M et al JACC 2011

Fazit für die Praxis

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Screening für Vorhofflimmern in Devices erbringt eine signifikante Detektionsrate von Vorhofflimmern. In den aktuellen Leitlinien wird eine Dauer von mindestens 30 s gefordert.

Detektion von Vorhofflimmern ist mit einem erhöhten Risiko für Schlaganfälle/TIA verbunden, das von der Dauer des Vorhofflimmerns, aber auch dem zugrundeliegenden Risikoprofil beeinflusst wird.

Retrospektive Analysen zeigen einen deutlichen Anstieg des Schlaganfallrisikos nach Detektion von mindestens 1 h Vorhofflimmern.

Nach kryptogenem Schlaganfall haben Patienten nach 3 Jahren eine Vorhofflimmerinzidenz von 30%, von denen 90% über 6 Minuten und 65% über 6 Stunden lag. Bei Nachweis von Vorhofflimmern wurde zu 90% mit einer oralen Antikoagulation begonnen.

Bisher konnte kein zuverlässiger Nachweis einer Korrelation zwischen dem Auftreten von Vorhofflimmern und dem konsekutiven zeitnahen Eintreten eines thrombembolischen Ereignisses nachgewiesen werden.

In der Praxis wird die Entscheidung zur oralen Antikoagulation nicht nur von der Dauer, sondern auch von dem Risikoprofil im CHADS-Vasc Score abhängen, vor allem vom Alter und der Anamnese eines Schlaganfalls.

Laufende prospektive Studien werden die Indikationsstellung zur OAK bei Vorhofflimern präzisieren.