



## **23. Lenzburger Fortbildung**

### **Der Mensch im medizinischen Netz(werk)**

22. Oktober 2015

# **Kontinuierliche Rhythmusüberwachung und Rhythmusdiagnostik mit implantierbaren Monitoren**

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## Agenda:

- Was sind implantierbare Rhythmusmonitore?
- Wie aufwändig ist die „Operation“?
- Wann sind diese Systeme indiziert?



## Implantierbare Rhythmusmonitore/Ereignisrecorder

CareLinq  
Medtronic

Biomonitor II  
Biotronik

Confirm  
St. Jude Med.





## Implantierbare Rhythmusmonitore/Ereignisrecorder

- Überwachen bis zu 3.5 Jahre den Herzrhythmus und speichern Arrhythmien nach programmierten Kriterien (zB.: Vorhofflattern/-flimmern und Tachyarrhythmie  $> 140/\text{min}$  und/oder Bradycardie  $< 40/\text{min}$  und Asystolie)
- Senden zT. automatisch täglich via Mobilfunknetz EKGs als e-mail mit Arrhythmien, die die definierten Kriterien erfüllen



## Implantierbare Rhythmusmonitore/Ereignisrecorder



Lokalanästhesie links parasternal, ambulanter Eingriff, Praxis oder Spital







# Implantierbare Rhythmusmonitore/Ereignisrecorder



Absender	Betreff	Empfangen
<i>Santesuisse e-mail list</i>	<i>Spezialkurse Santesuisse</i>	Heute 10:32
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:55
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:46
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:44
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:43
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:12
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:11
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:02
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 09:01
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Red Alert.	Heute 08:55
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 08:46
CareLinkSupport@medtronic.com	Medtronic CareAlert@ transmission received Yellow Alert.	Heute 08:40



# Implantierbare Rhythmusmonitore/Ereignisrecorder

## Indikationen





## Fallbeispiel 1

- 62 jährige Patientin meldet sich wegen passagerer Sehstörung und Herzrasen

# **TIA bei Paroxysmalem Vorhofflimmern?**

- Vorgeschichte: Art. Hypertonie



## Fallbeispiel 1: Abklärungen

- Neurostatus unauffällig
- 12-Kanal-EKG: Sinusrhythmus, F 72/min, Normalbefund
- TSH normal
- 24h-LZ-EKG normal



## Fallbeispiel 1

# Ist Paroxysmales Vorhofflimmern jetzt ausgeschlossen?

unangenehme Herzrasen gehabt

- Nochmals EKG: keine Veränderung
- Nochmals LZ-EKG 48h:  
Sinusrhythmus, keine relevanten  
Arrhythmien

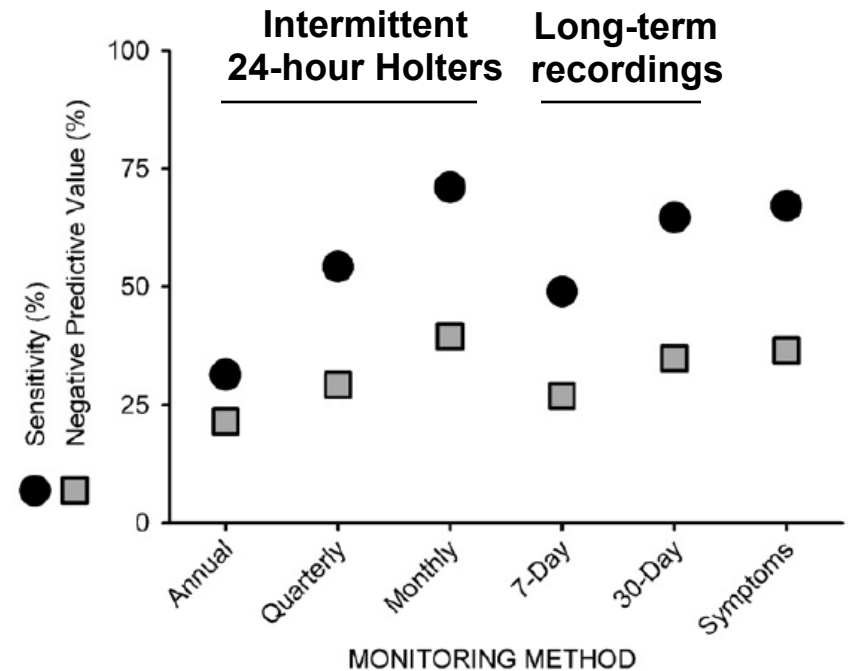
# Clinical Relevance of Atrial Fibrillation (AF)

Reference	Message	Clinical Consequence
Camm AJ, EHJ 2010	AF increases a patients risk for stroke	Patient with AF are 5 times more likely to experience stroke
Page RL, Circ 1994	AF can be asymptomatic	Rates of asymptomatic AF are more frequent than symptomatic AF
Israel CW, JACC 2004	Asymptomatic AF is common	1/3 <sup>rd</sup> of AF episodes are asymptomatic
Healey JS, NEJM 2012	Asymptomatic AF is associated with stroke	Asymptomatic AF is associated with a 2.5 fold increase in risk of stroke and systemic embolism
Boriani G, CirCardQuaOutcomes 2012	Adherence to stroke prevention in AF guidelines is low	54% of patients were indicated but not taking OAC

# Comparison of intermittent, symptom-based and continuous monitoring to detect atrial fibrillation

- 574 pacemaker patients were followed for 1 year.
- Intermittent monitoring (24hr Holter 1, 4, 12 times per year and 7-day and 30-day once per year) was evaluated.
- Intermittent and symptom-based monitoring had significantly lower sensitivity and negative predictive value.

Sensitivity and Negative Predictive value for identification of patients with AT/AF



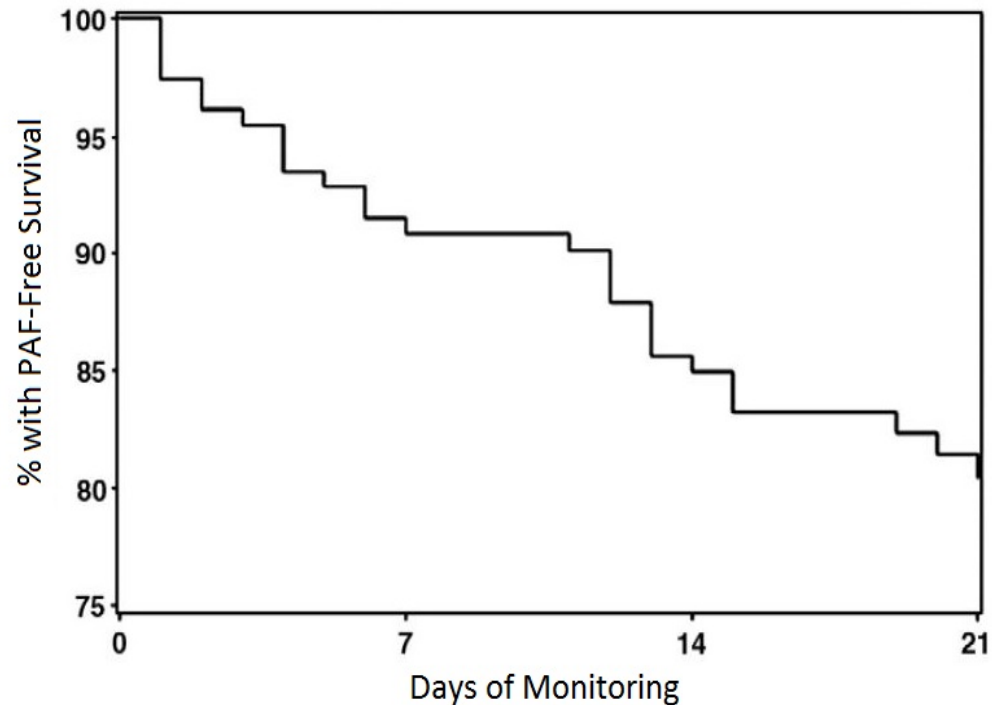
all  $p < 0.001$  vs. Continuous Monitoring

Ziegler P, et al. Heart Rhythm 2006; 3:1445-1452



# Diagnosing atrial fibrillation for Secondary Prevention of Stroke

- 156 patients with an ischemic stroke or TIA with an unidentified cause
- Median monitoring duration was 21 days
- AF occurred in 17% of the patients within 3 weeks.
- Optimal length of monitoring is yet to be established

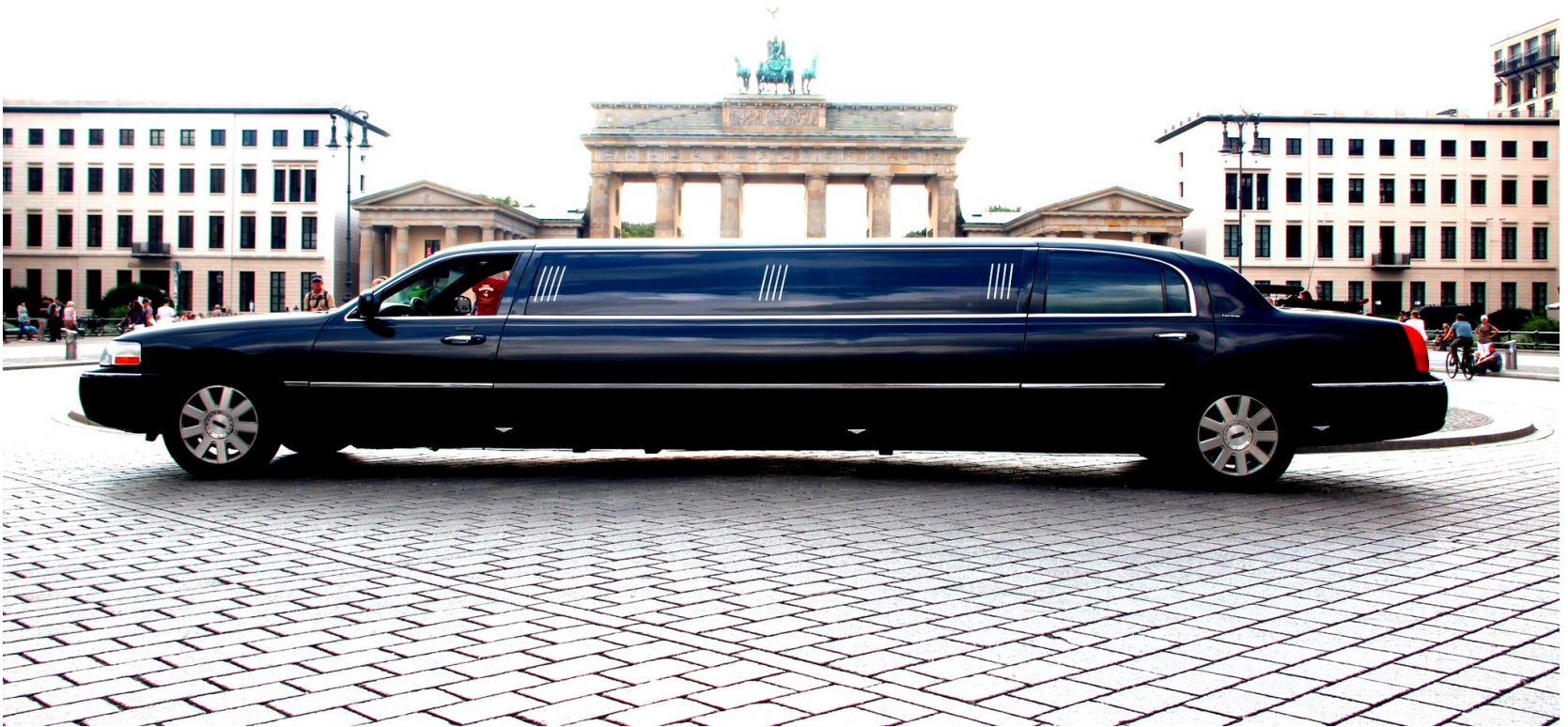


The rate of AF detection significantly increased from 3.9% in the initial 48 h, to 9.2% at 7 days, 15.1% at 14 days, and 19.5% by 21 days ( $p < 0.05$ )

Miller DJ, et al. J Neurological Sciences 2013; 324: 57-61



## Suche nach paroxysmalem Vorhofflimmern: Wie lang ist lang genug?



# Zielsetzung CRYSTAL AF Studie

Ist eine Langzeit-Monitoring-Strategie mit einem *Implantierbaren Herzmonitor (ICM)* im Vergleich zum bisherigen Standardvorgehen überlegen, um:

- a) Vorhofflimmern (AF) bei Patienten mit cryptogenem Schlaganfall zu detektieren nach **6 Monaten** (primary end point) und **12 Monaten** follow-up (secondary end point)
- b) Den Anteil der Patienten mit cryptogenem Insult zu bestimmen, die AF haben
- c) Die Behandlungskonsequenz OAK zu erreichen nach Diagnose von AF

# Einschluss-/Ausschlusskriterien

## Inclusion:

- $\geq 40$  years of age
- Cryptogenic stroke (or clinical TIA), with infarct seen on MRI or CT, within the previous 90 days; and no mechanism (including AF) determined after:
  - 12-lead ECG
  - 24-hour ECG monitoring (e.g. Holter)
  - Transesophageal echocardiography (TEE)
  - CTA or MRA of head and neck to rule out arterial source
  - Screening for hypercoagulable states in patients  $< 55$  years old

## Exclusion:

- History of AF or Atrial Flutter
- Permanent indication or contraindication for anticoagulation
- Indication for pacemaker or implantable cardioverter defibrillator

# Patienten Follow-up

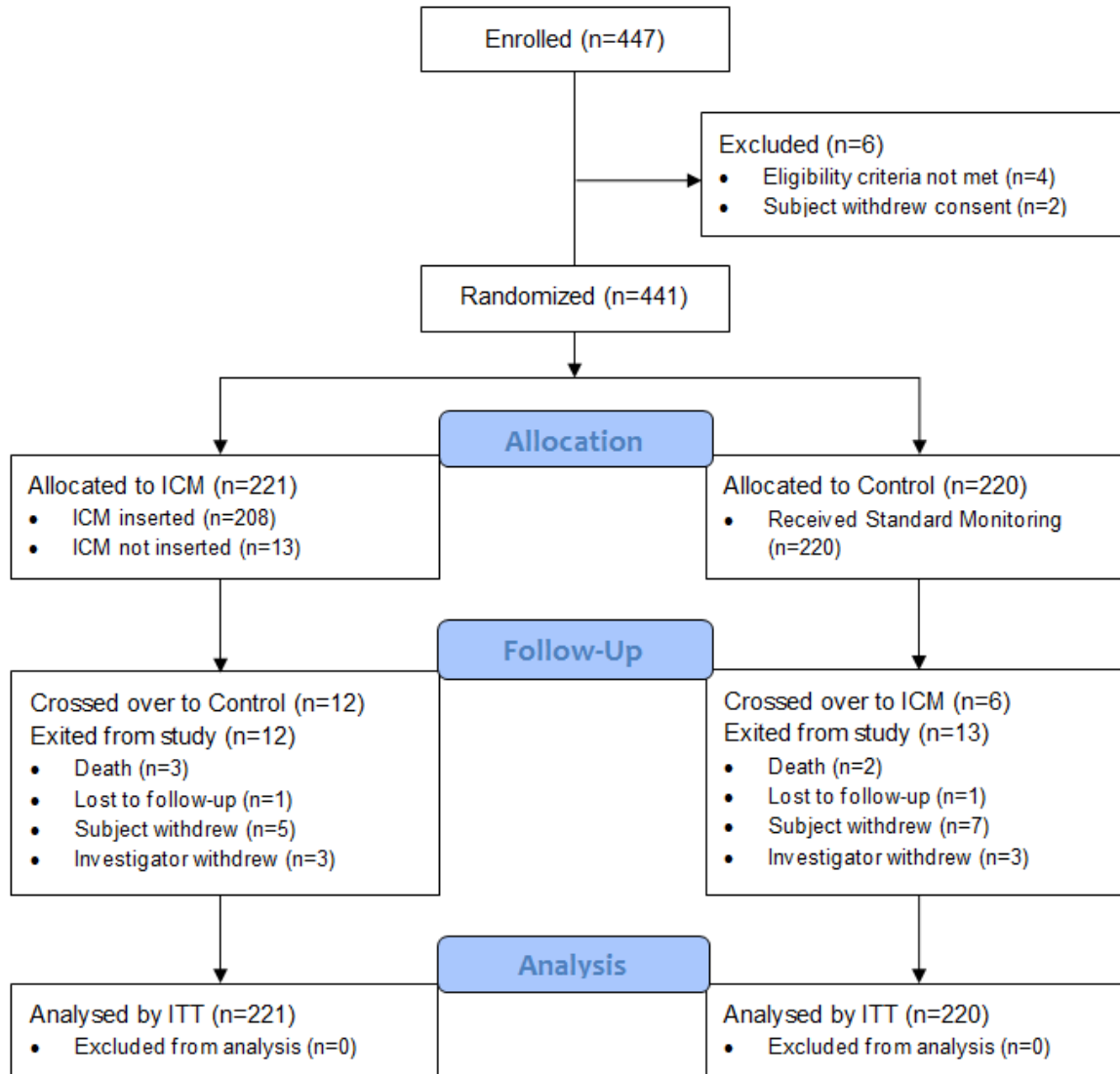
- Patients in both arms received scheduled follow-up visits at:
  - 1 month
  - 6 months
  - 12 months
  - Every 6 months thereafter until study closure
- Follow-up visits recorded:
  - Cardiac symptoms
  - Treatment modifications
  - Recurrence of stroke or TIA
  - Modified Rankin Scale
  - Health status (EQ-5D)



# Methoden

- Vorhofflimmern (AF) definiert als eine Episode von unregelmässigem Herzrhythmus ohne erkennbare P-Wellen, die länger als 30s andauert
- AF Episoden wurden durch den Kardiologen des Patienten identifiziert und durch ein unabhängiges Studiengremium verifiziert

# Patient Flow

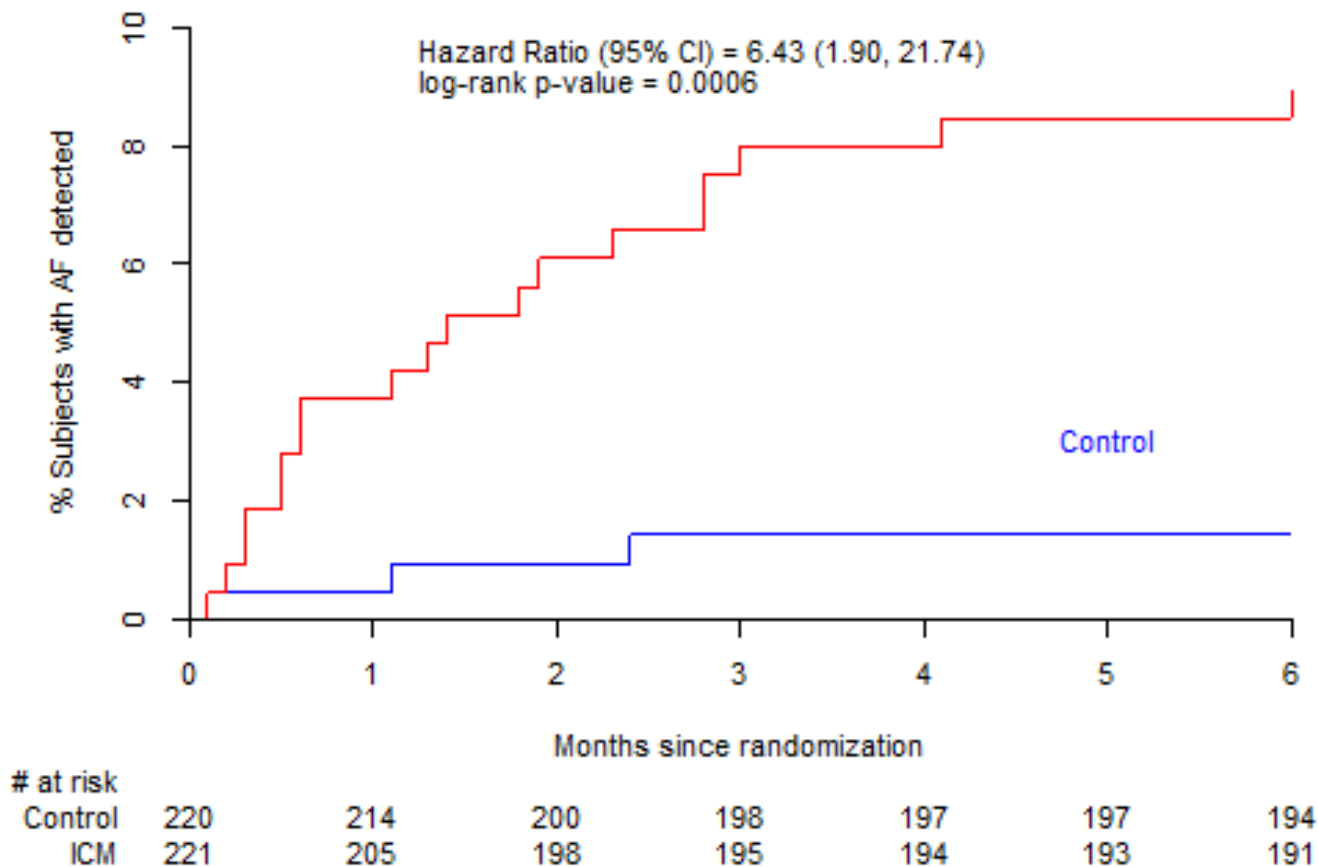


# Baseline Characteristics:

	ICM	Control
Age	61.6 ± 11.4 years	61.4 ± 11.3 years
Gender - Male	142 (64.3%)	138 (62.7%)
Index Event – Stroke	200 (90.5%)	201 (91.4%)
Index Event – TIA	21 (9.5%)	19 (8.6%)
Pre-enrollment AF screening – Holter Monitoring	71.5% of patients Median of 23 hours (IQR 21-24)	70.9% of patients Median of 24 hours (IQR 22-24)
Pre-enrollment AF screening – Telemetry	29.9% of patients Median of 48 hours (IQR 36-96)	29.5% of patients Median of 72 hours (IQR 48-96)
Time between index event and randomization	36.6 ± 28.2 days	39.6 ± 26.9 days
Time between randomization and device insertion	8.7 ± 27.6 days	n/a

# Primary Endpoint: Detection of AF at *6 months*

## ICM finds 6x more patients with AF



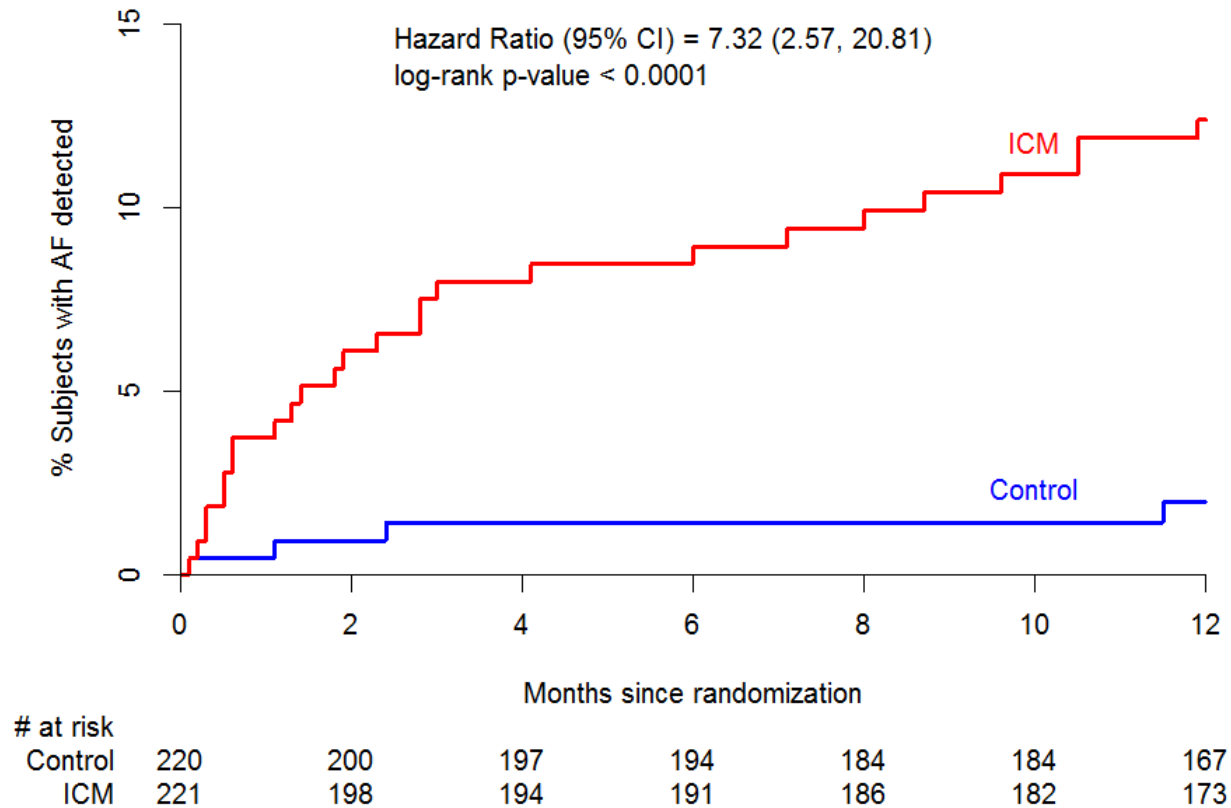
Sanna T, Diener HC, Passman RS, et al. Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF).  
*N Engl J Med.* 2014; 370(26):2478-2486

# 6 Month Endpoints

	ICM	Control
Median time from randomization to AF Detection	41 days	32 days
Patients found to have AF	19	3
% Asymptomatic Episodes	74%	33%
Oral Anticoagulation (OAC) Usage, overall	10.1%	4.6%
OAC use in patients with detected AF	94.7%	66.7%
Recurrent Stroke/TIA	5.2%	8.6%
Proportion of patients with AF $\geq$ 6 minutes on one day	93.8%	N/A
Tests required to detect AF	Automatic AF detection	88 ECGs 20 24-hour Holters 1 event recorder



# Secondary Endpoint: Detection of AF at *12 months* ICM finds 7x more patients with AF



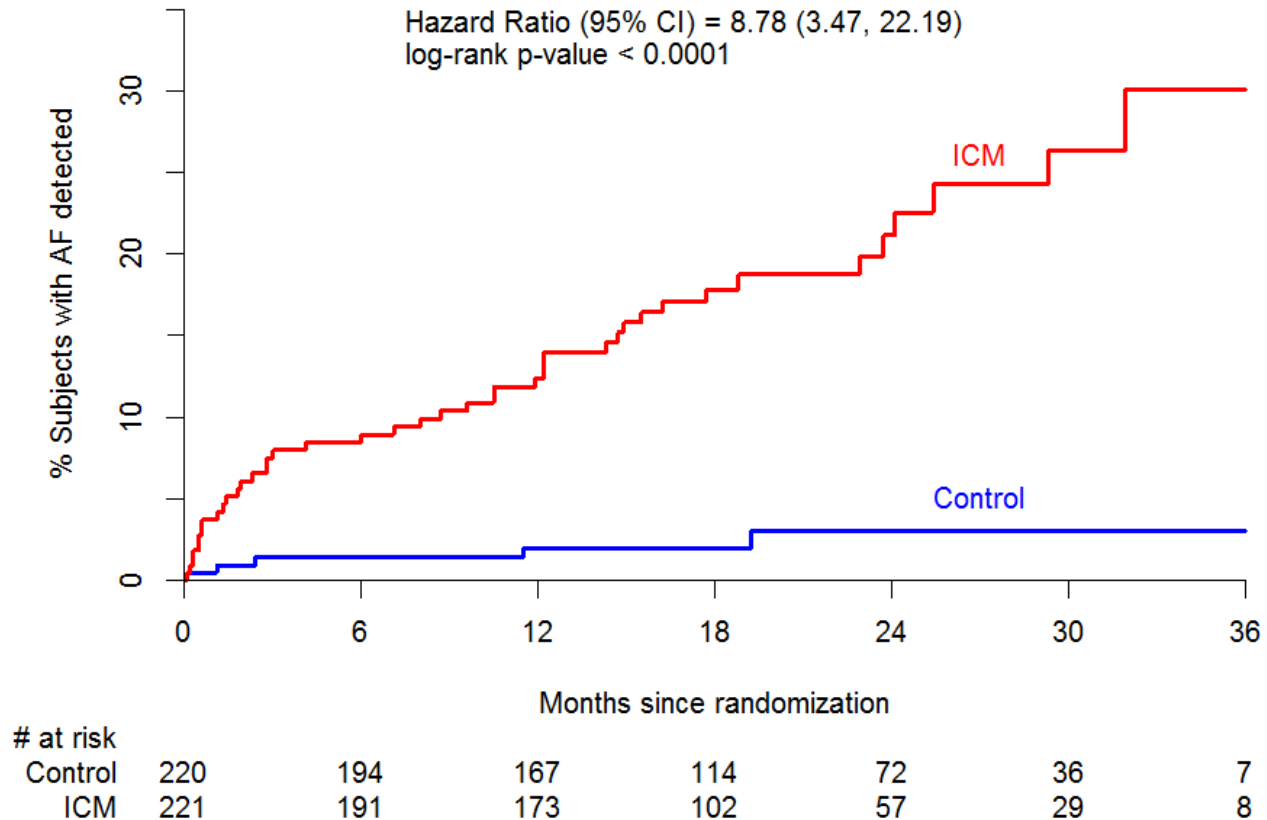
Sanna T, Diener HC, Passman RS, et al. Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF).  
*N Engl J Med.* 2014; 370(26):2478-2486

# 12 Month Endpoints

	ICM	Control
Median time from randomization to AF Detection	84 days	52.5 days
Patients found to have AF	29	4
% Asymptomatic Episodes	79%	50%
Oral Anticoagulation (OAC) Usage, overall	14.7%	6.0%
OAC use in patients with detected AF	96.6%	100%
Recurrent Stroke/TIA	7.1%	9.1%
Proportion of patients with AF $\geq$ 6 minutes on one day	92.3%	N/A
Tests required to detect AF	Automatic AF detection	121 ECGs 32 24-hour Holters 1 Event Recorder

# Detection of AF at *36 months*

## ICM finds 8.8x more patients with AF



Sanna T, Diener HC, Passman RS, et al. Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF).  
*N Engl J Med.* 2014; 370(26):2478-2486

# 36 Month Data

	ICM	Control
Median time from randomization to AF Detection	252 days	72 days
Patients found to have AF	42	5
% Asymptomatic Episodes	81%	40%
Oral Anticoagulation (OAC) Usage, overall	38.5%	8.3%
OAC use in patients with detected AF	90%	80%
Recurrent Stroke/TIA	11.1%	12.7%
Proportion of patients with AF $\geq$ 6 minutes on one day	94.9%	N/A
Tests required to detect AF	Automatic AF detection	202 ECGs, 52 Holter Monitors, 1 Event Recorder

# Schlussfolgerungen Crystal AF

**Kontinuierliches Monitoring mit einem implantierbarem Ereignisrecorder ist dem bisherigen Standard (EKG plus rez. Langzeit-EKGs) überlegen um Vorhofflimmern bei Patienten nach cryptogenem Insult nachzuweisen**

**Die Studie zeigt dass:**

- 1. Kontinuierliches Monitoring sieben mal häufiger Vorhofflimmern innert 12 Monaten nachweist (primärer Endpunkt).**
- 2. Bei der Nachverfolgung der Patienten über drei Jahre konnte bei 30% der Patienten mit implantierbarem Ereignisrecorder Vorhofflimmern nachgewiesen werden, hingegen nur bei 3% in der Standard Monitoring Gruppe.**
- 3. Ein Kurzzeit- Monitoring (EKG, Langzeit-EKG) ist nicht ausreichend, da die mittlere Zeit bis zum Nachweis von AF innert 12 Monaten follow-up 84 Tage betrug.**
- 4. 97% der Patienten, bei denen AF nachgewiesen wurde, wurde eine OAK verschrieben**

**Vorhofflimmern:  
symptomatisch 19% vs. asymptomatisch 81%**





## Fallbeispiel 1

**Die Implantation eines  
Ereignisrecorder ist bei dieser  
Patientin sinnvoll**

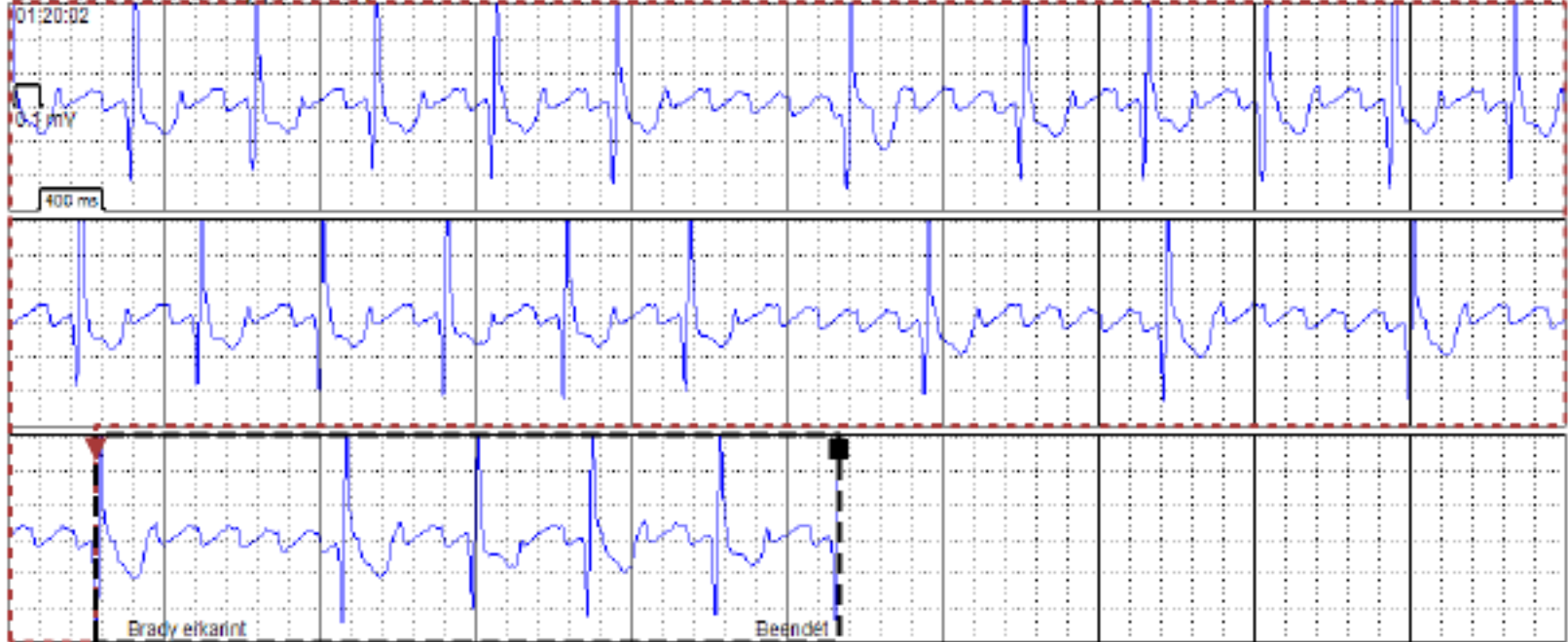
- Nochmals LZ-EKG 48h:  
Sinusrhythmus, keine relevanten  
Arrhythmien





# Fallbeispiel 1      Diagnose: Vorhofflimmern

EKG-Übersicht: Brady (ID-Nr. 67)







## Fallbeispiel 2

- 76 jährige Patientin meldet sich weil sie in der Küche hingefallen ist und kurz weg war
- Bluterguss Hüfte und Stirn



## Fallbeispiel 2: Abklärungen

- 12-Kanal-EKG: Sinusrhythmus, F 62/min, Normalbefund
- Röntgen: keine Fraktur
- 24h-LZ-EKG: keine Pathologie



## Fallbeispiel 2

- Nach 2 Monaten meldet sich die Patientin wieder. Ist auf der Strasse hingefallen, war kurz schwindlig vorab. Jetzt alles wieder gut
- Nochmals EKG: keine Veränderung
- LZ-EKG 24h: Sinusrhythmus, keine relevanten Arrhythmien



## Fallbeispiel 2

# Und jetzt? Wie

weiter?

Gar nichts passiert, nur Schürfwunde am Arm. Will wissen, ob Frau deswegen zum Arzt soll

# Continuous Monitoring of **Unexplained Syncope**



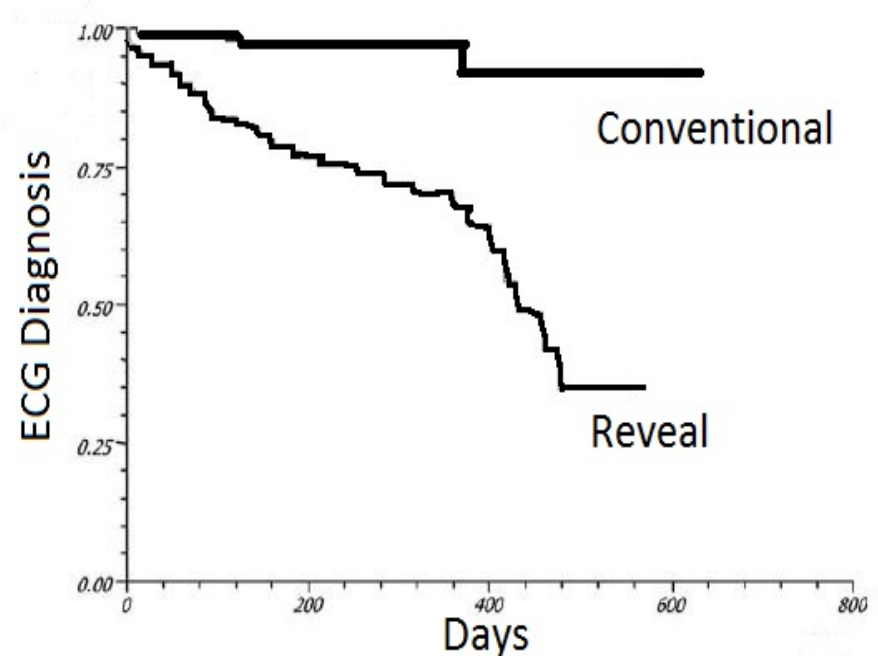
# Clinical Relevance, Application & Benefit of Implantable Rhythm Monitoring (**IRM**) for Syncope

Reference	Marketing Message	Clinical Message
Moya A, EHJ 2009	Syncope puts the patient at risk	Patient with cardiac syncope are twice as likely to die
Farwell DJ EHJ 2004	Timely diagnosing in unexplained syncope	In patients with recurrent syncope <b>IRM</b> patients are 9 times more likely to reach an ECG diagnosis that conventional investigation
Giada F JACC 2007	Symptom and rhythm correlation in unexplained infrequent palpitations	<b>IRM</b> had a higher diagnostic value (73% vs 21%) than Holter or event recorder monitoring
Petkar S Europace 2012	Differential Diagnosis between Epilepsy and Convulsive Syncope	67% of the patients previously diagnosed with epilepsy had T-LOC symptom/ECG correlation established by <b>IRM</b> recording
Velu S Poster HRC, 2012	Reveal combined with remote monitoring for even faster diagnostic effectiveness	47% reduction in mean time from <b>IRM</b> to diagnosis in the remote monitored group

# Timely Diagnosis in Unexplained Syncope

- EaSyAS Study
- 201 patients with recurrent, unexplained syncope were randomized to **IRM** or conventional investigation
- 33% of the **IRM** patients and 4% of the conventional patients had an ECG diagnosis (HR 8.9,  $p < 0.001$ ).
- Introduction of ECG-directed therapy was quicker for **IRM** patients (HR 7.9,  $p < 0.001$ ).

Time to ECG Diagnosis



Farwell DJ, et al. EBJ 2004; 25:1257-1263

# Differential Diagnosis between Epilepsy and Convulsive Syncope

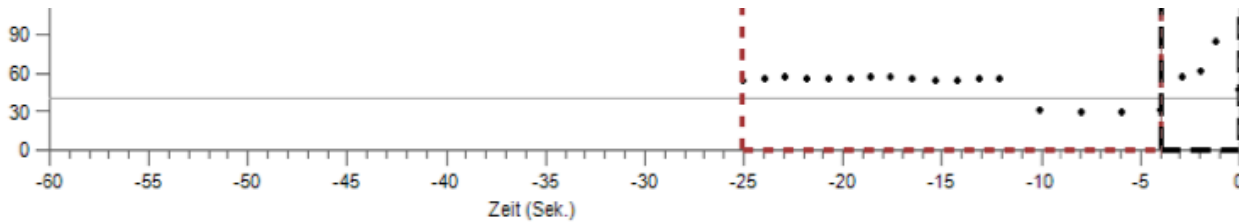
- REVISE Study
- 103 patients previously diagnosed with epilepsy, but suspected to have a misdiagnosis and implanted with a **IRM** were evaluated.
- 67% of the patients had T-LOC symptom/ECG correlation established by **IRM** recording

Implantable electrocardiographic recorder data	
	Whole cohort, N = 103 (%)
.....	
Duration of follow-up after ILR (days): mean $\pm$ standard deviation, range	874 $\pm$ 776, 6–3360
ECG symptom correlation achieved in	69 (67.0)
<i>Findings</i>	
Sinus arrest	13 (12.6)
Sinus arrest with AV block	5 (4.9)
Tachy-brady syndrome	2 (1.9)
Severe symptomatic sinus bradycardia	2 (1.9)
Normal sinus rhythm	43 (41.8)
Muscle artefacts S/o TCS	4 (3.9)

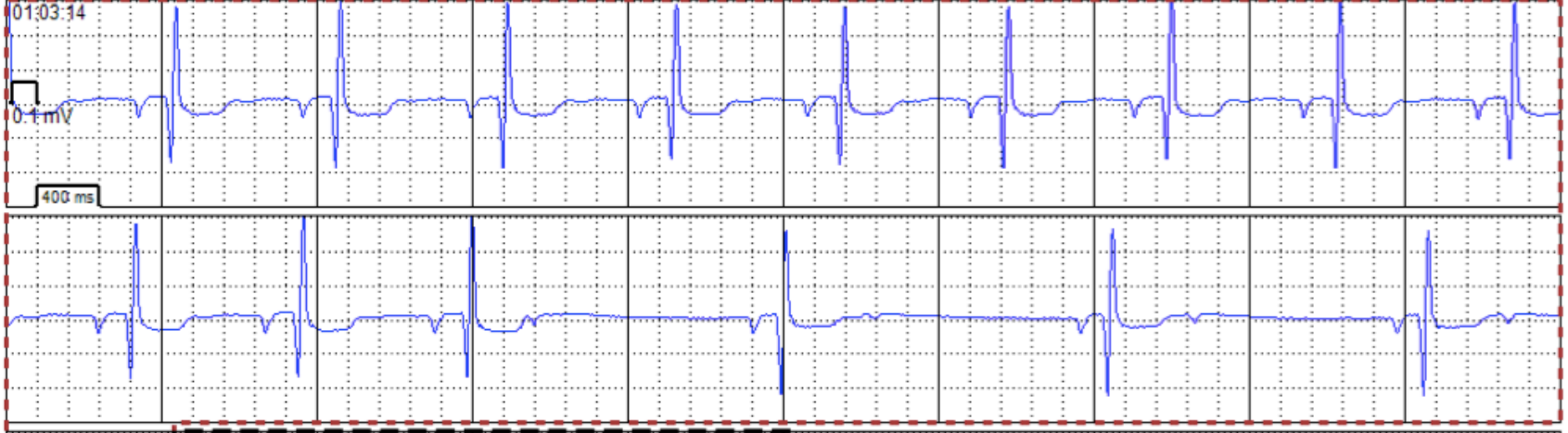
Petkar S, et al. Europace 2012; 14:1653-1660



## Fallbeispiel 2      Diagnose: Ausfall P-Welle



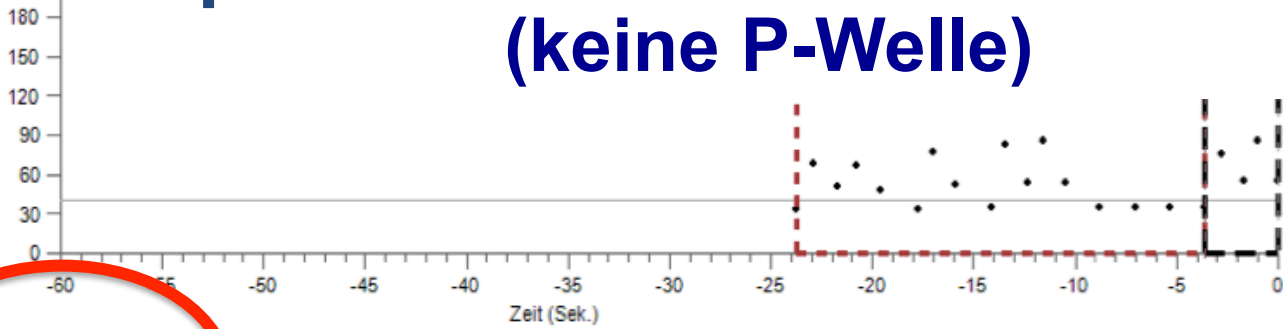
EKG-Übersicht: Brady (ID-Nr. 123)



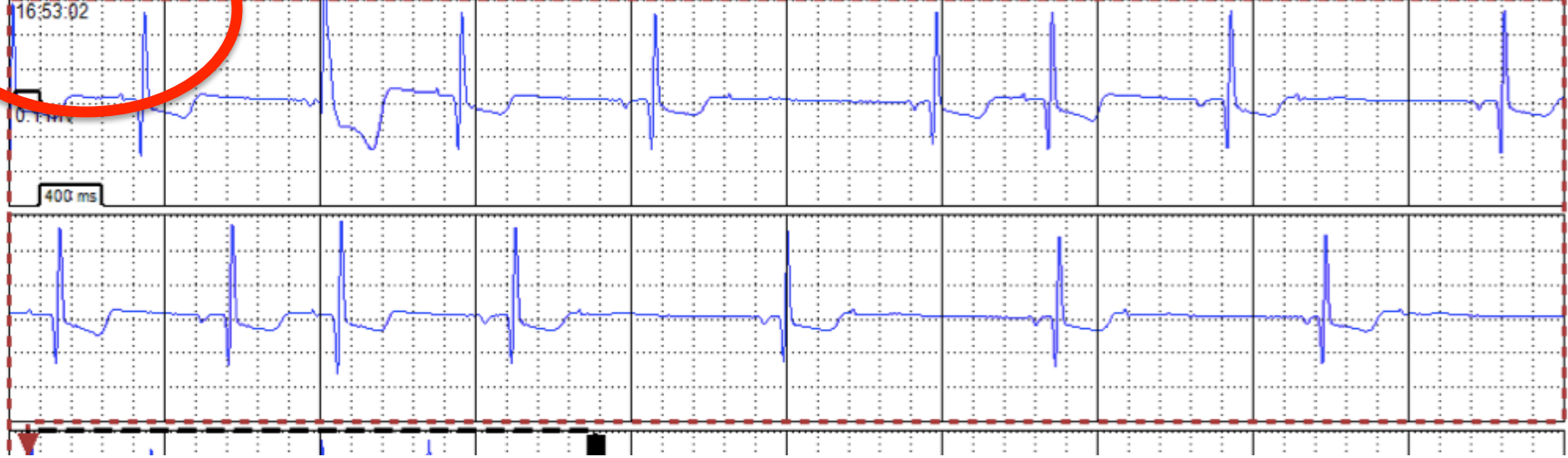


# Fallbeispiel 2      Diagnose: intermitt. Sinusarrest (keine P-Welle)

p: 16  
36 min<sup>-1</sup>  
q.: 36 min<sup>-1</sup>



EKG-Übersicht: Brady (ID-Nr. 219)

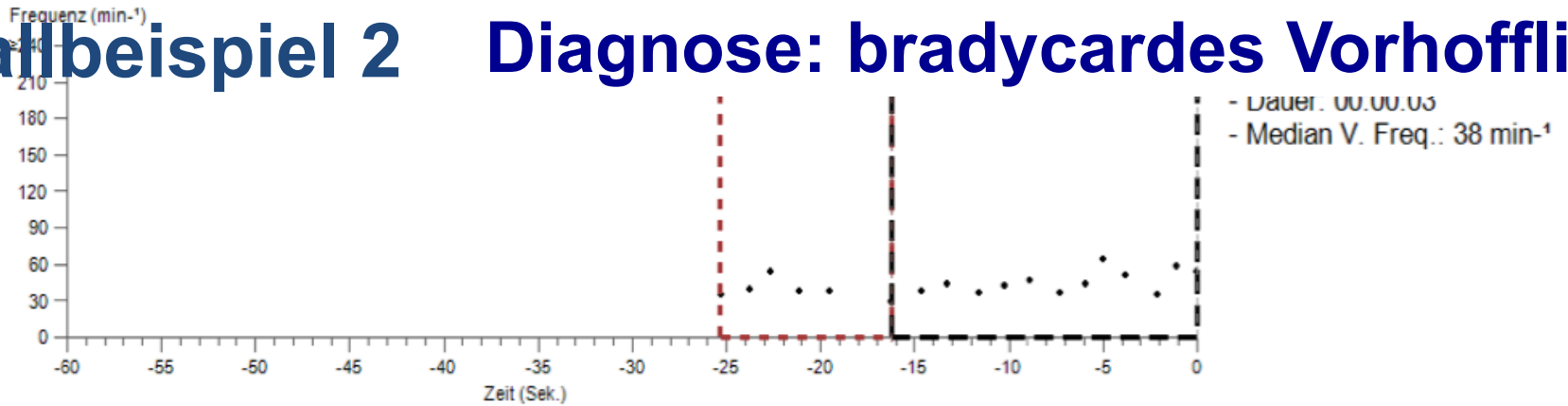




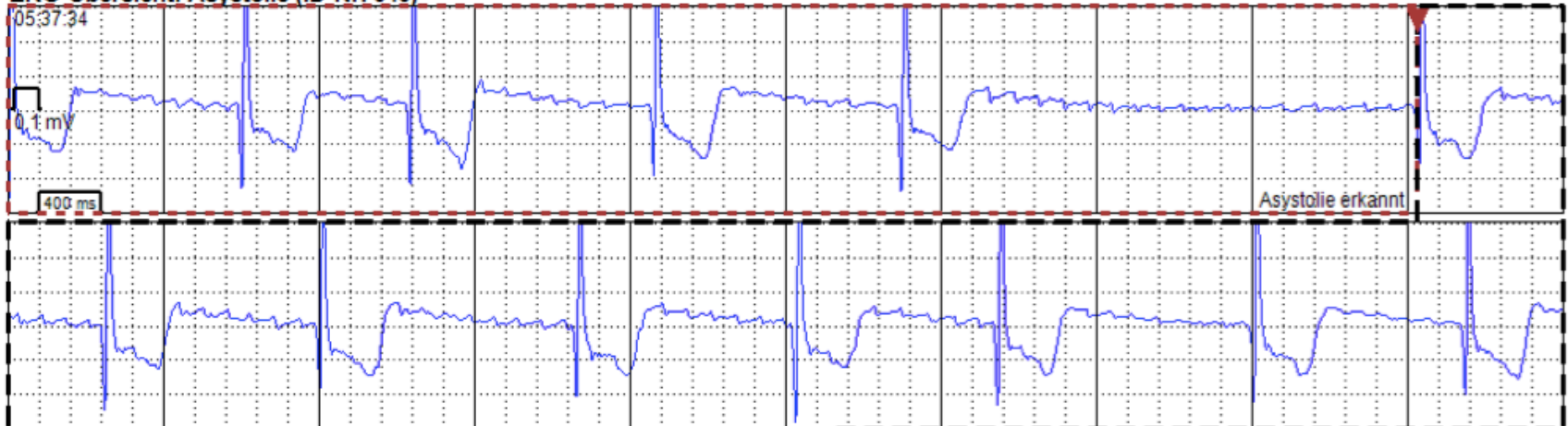


## Fallbeispiel 2

## Diagnose: bradycardes Vorhofflimm

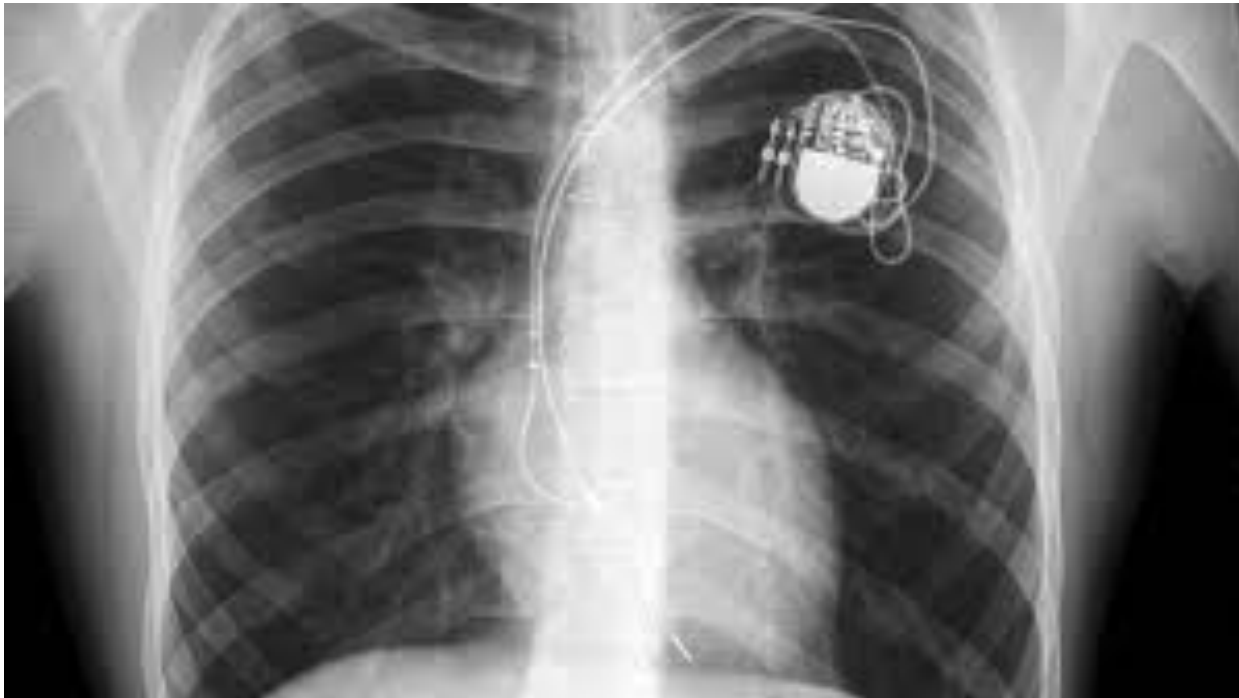


### EKG-Übersicht: Asystolie (ID-Nr. 346)





## **Fallbeispiel 2: PM-Implantation Ereignisrecorder-Explant**







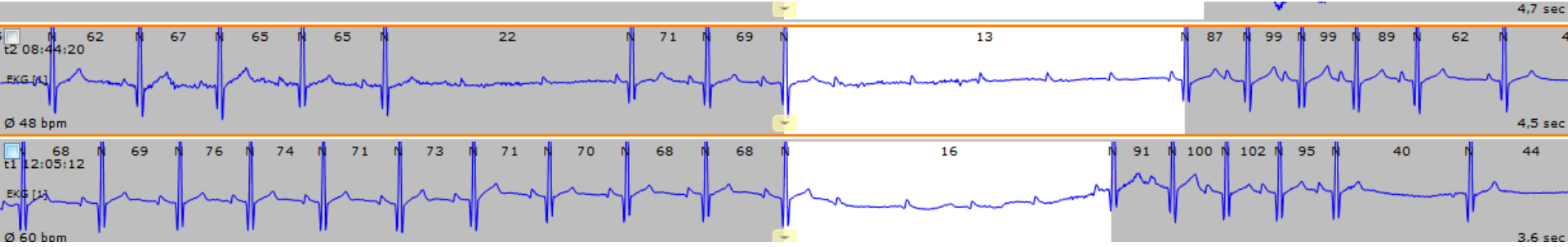
# Schlussfolgerungen

Implantierbare Rhythmusmonitore sind eine sinnvolle Ergänzung des diagnostischen Repertoires bei der Suche nach paroxysmalem Vorhofflimmern und bei der Abklärung von rezidivierenden Synkopen

Implantierbare Rhythmusmonitore sind keine „first line“-Diagnostik, sondern werden erst nach Basisdiagnostik mit EKG und > 2 LZ-EKGs in Betracht gezogen

# **Vorhofflimmern: Diagnose vor dem Insult stellen!**





# Evolution der Rhythmusdiagnostik



# Evolution der Rhythmusdiagnostik



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