6. Zentralschweizer Kardiologie Symposium Luzern

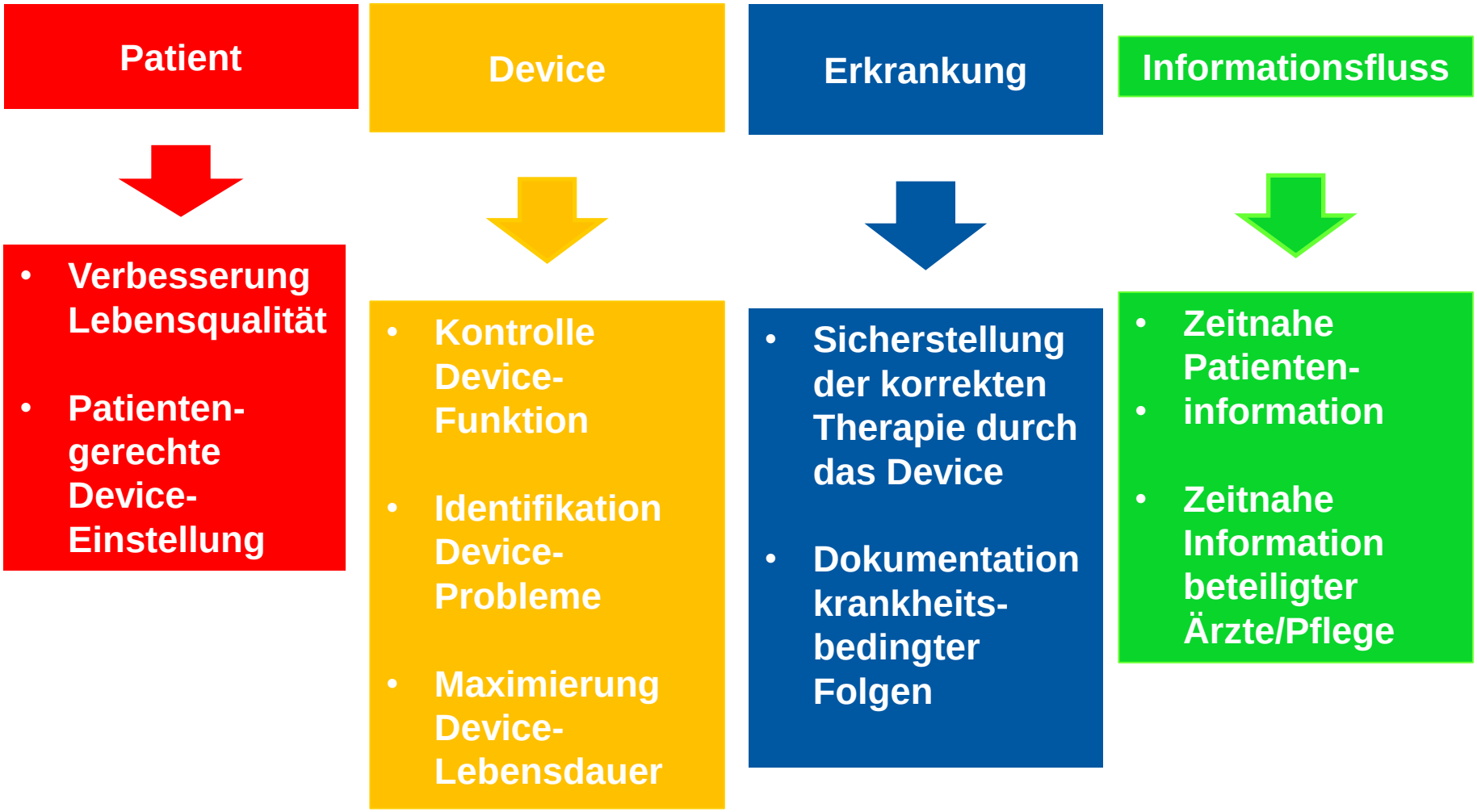
Telemedizin in der Rhythmologie
Bedeutung und Risiken im Praxisalltag

Corinna Brunckhorst
Universitäres Herzzentrum Zürich

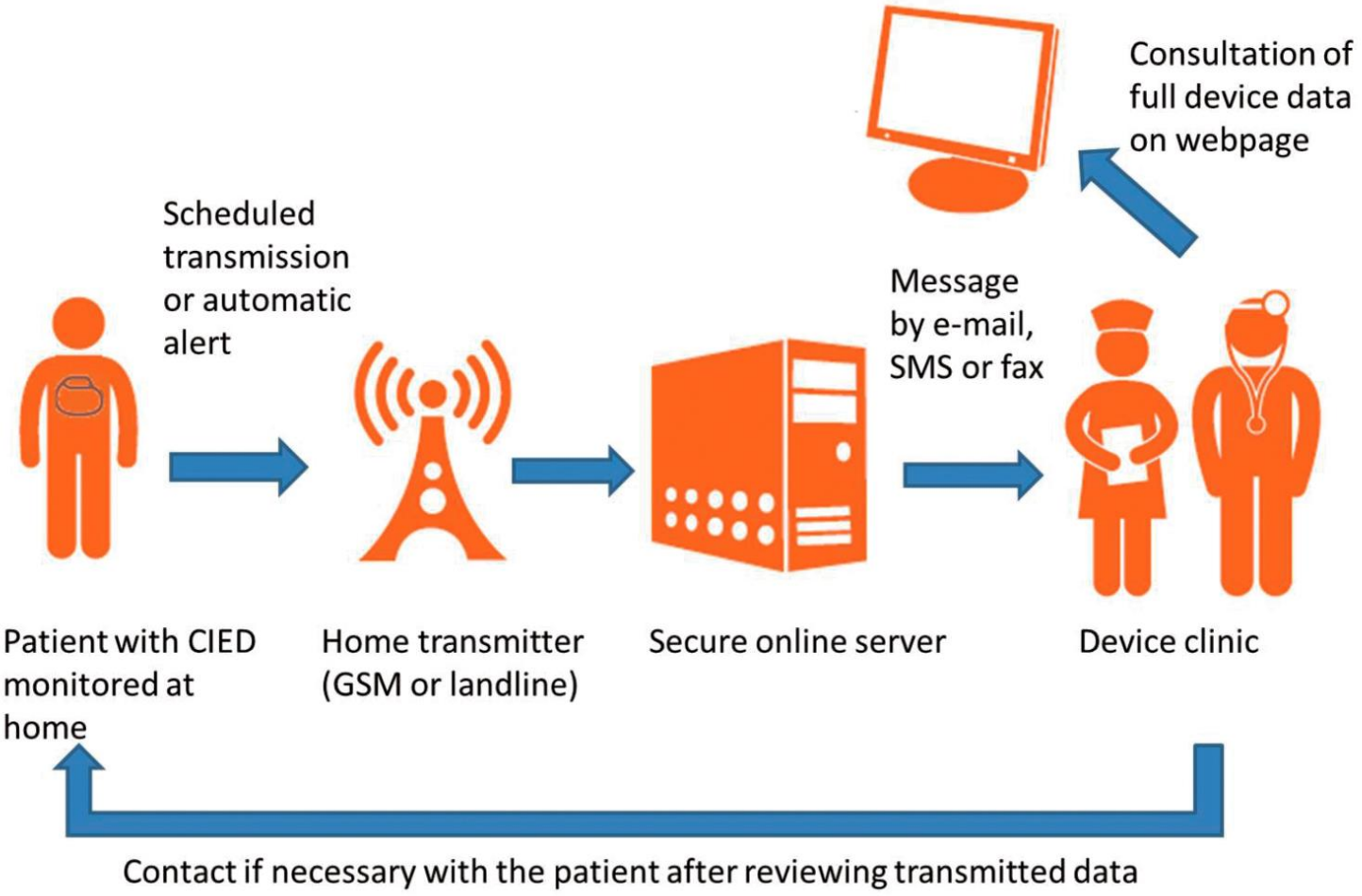
23. Mai 2019

Telemedizin

Telemedizin in der Rhythmologie



Telemedizin Setting



Burri et al. *Arrhythmia & EP* 2013*; 2: 95-98*

Therapeutische Devices

ICDs

CRT-Ds and CRT-Ps

Pacemakers

In-office interrogation

Taieb, J., et al. (2013). ICD in the Era of Telecardiology.

Telemedizin: Therapeutische Devices

ICDs

CRT-Ds and CRT-Ps

Pacemakers

Remote monitoring (RM) system

Patient Monitor

Streamlined Reports

Smart Monitor

Telemedizin: Diagnostische Devices

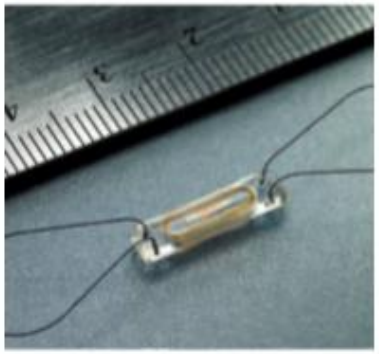
Insertable Cardiac Monitor

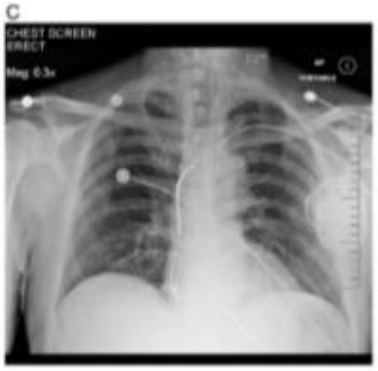
Remote monitoring (RM) system

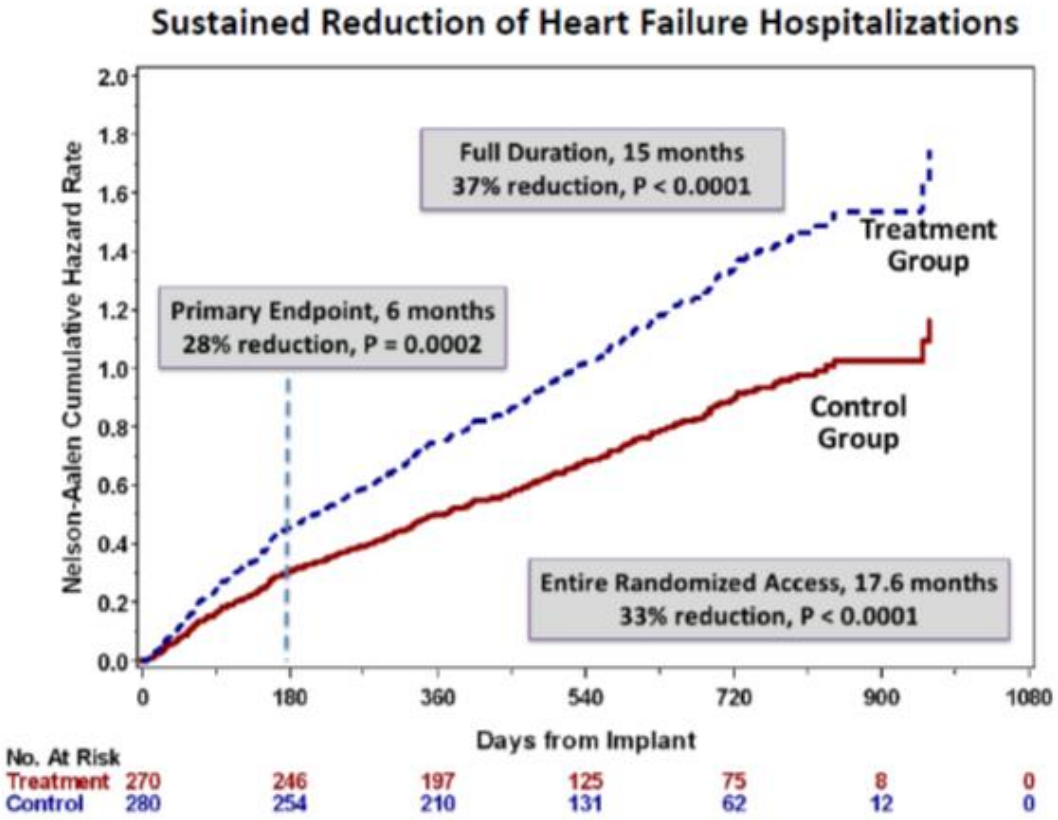
Patient Monitor

Streamlined Reports

Telemedizin: Diagnostische Devices
Pulmonary Artery Pressure Monitor
Champion Trial







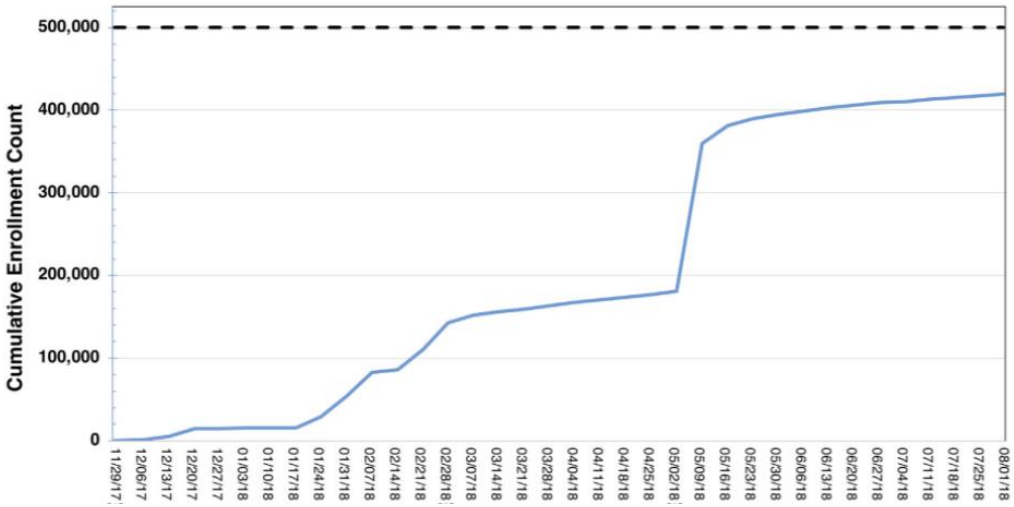
Abraham et al. Lancet 2015

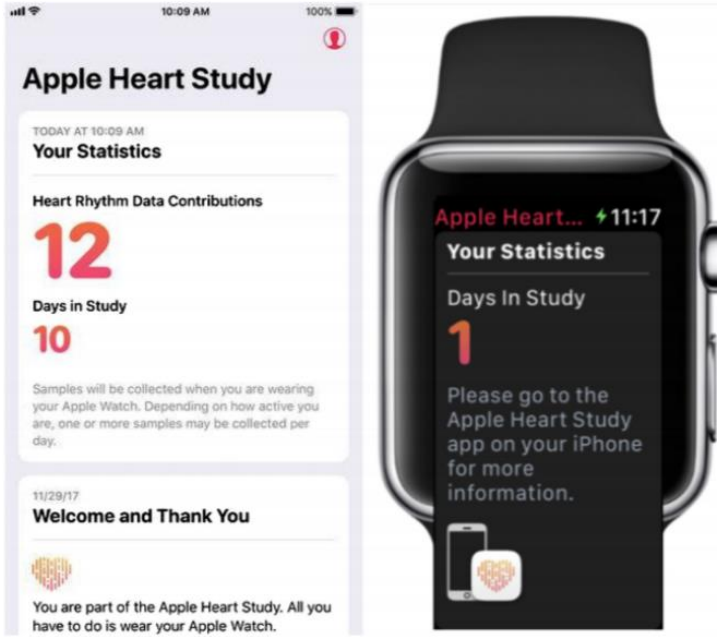
Internet-enabled mobile ECG (iECG)

ECG band for Apple Watch

Apple‘s Heart Study: Technology and Work Flow

Data collected in the home setting may not have the same quality controls as data collected within a clinical trial setting. Even though, this may provide new insights into the performance and clinical outcomes associated with medical device / drug use.





Explosion von Monitoring Devices verschiedenster biologischer Parameter mit digitaler Analyse und Datenübertragung

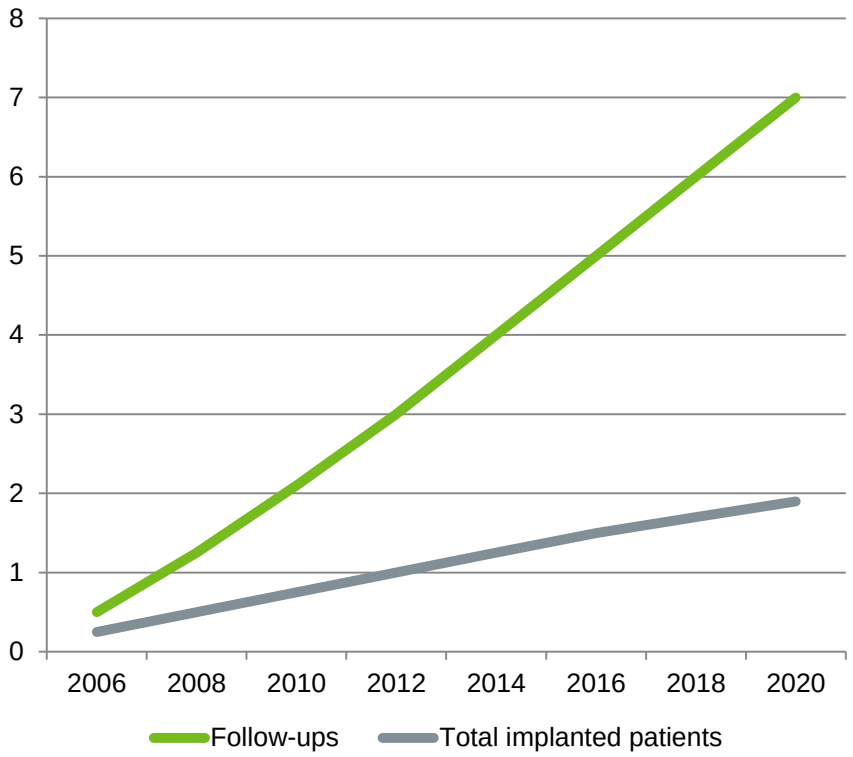
Herausforderung der Zukunft

"While there will always be more patients to manage. There will never
be more time to manage them."[1]

Gimbel, 2012

As the number of patients with implants increases, so does demand for follow-ups. **How can hospitals solve this growing challenge?**

EUROPE IMPLANTED PATIENTS & FOLLOW-UPS, 2006–2020[2] (MILLIONS)



1 Gimbel, 2012, Heart Rhythm, vol 9, n°12
2 Data from projected figures modelled using 2013/14 UK CRM NICOR dataset. https://www.ucl.ac.uk/nicor/nicor-news-publication/CRM_Report_2013-14

HRS Consensus Statement on Cardiac Device Remote Monitoring

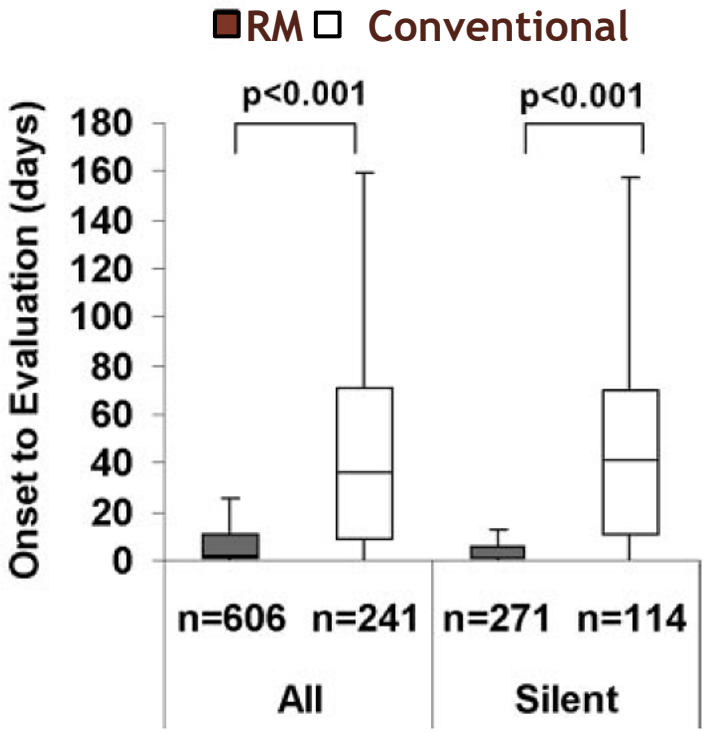
"Wireless remote monitoring has fundamentally changed the paradigm of how we care for patients with cardiovascular implantable electronic devices. **Randomized clinical trials have demonstrated that remote monitoring is superior** to a calendar-based schedule of periodic in-person device interrogations. Yet the rate of **adoption of the technology into clinical practice has varied widely."**[1]

LOCAL REIMBURSEMENT OFTEN DOES NOT CONFORM TO THIS STATEMENT, MEANING HOSPITALS ARE LESS INSENTIVISED TO ADOPT REMOTE MONITORING

2015 Consensus Statement: Remote Interrogation & Monitoring of Cardiovascular Implantable Electronic Devices

Zeitverlust: Detektion bis Evaluation

Median time from clinical event to evaluation[1]



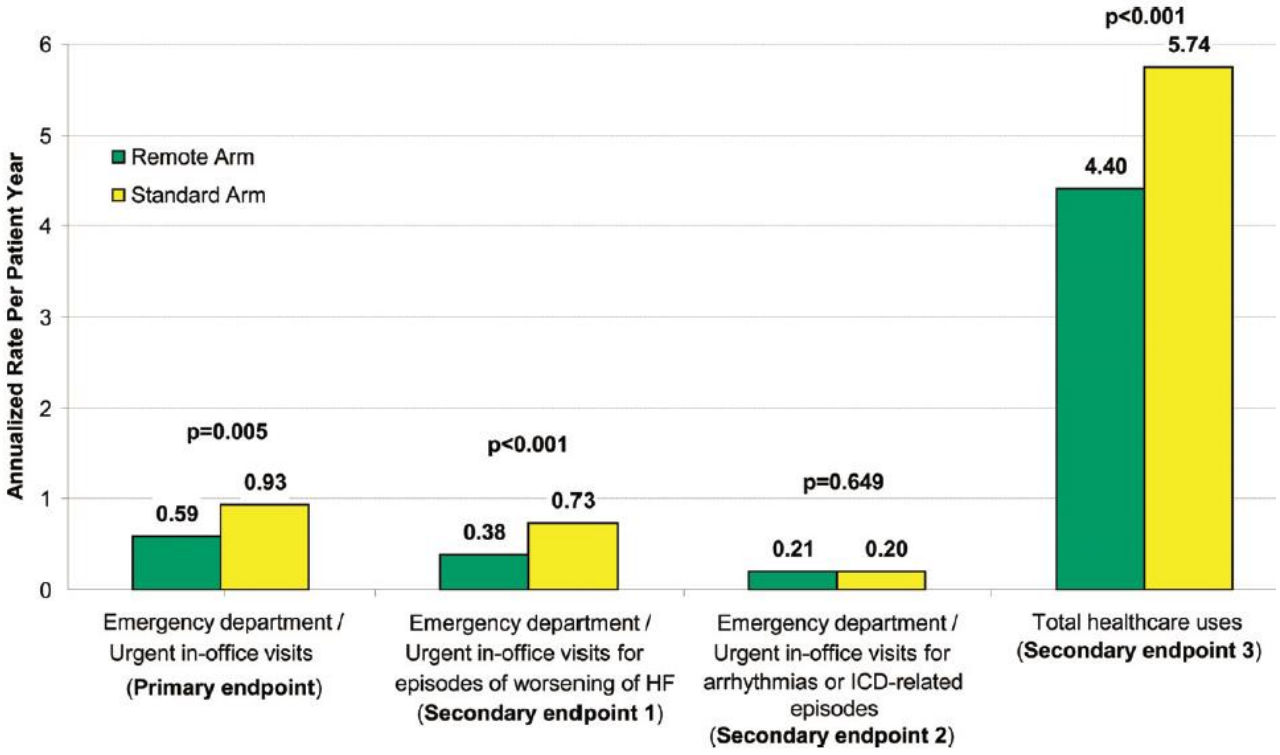
RM results in a substantial decreases in the time to detection/evaluation of clinical events

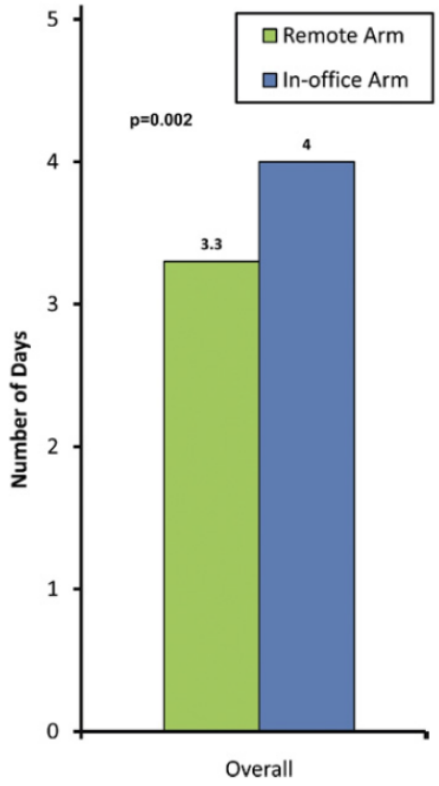
- **TRUST Trial (ICD patients)[1]**
  - 94% reduction in time from a clinical event to evaluation
- **CONNECT Trial (ICD/CRT-D patients) [2]**
  - 79% reduction in time from a clinical event to a clinical decision
- **MORE-CARE (CRT-D patients) [3]**
  - Clinical decisions were made 93% faster

1. *Circ Arrhythm Electrophysiol.* 2010;122:325-332.
2. J Am Coll Cardiol. 2011;57:1181-1189.
3. J Med Internet Res. 2013;15(8):e167.

Klinische Vorstellungen und Hospitalisationsdauer

In the EVOLVO trial, heart failure patients with an ICD or CRT-D had decreased emergency/urgent visits and total healthcare utilizations when followed by RM





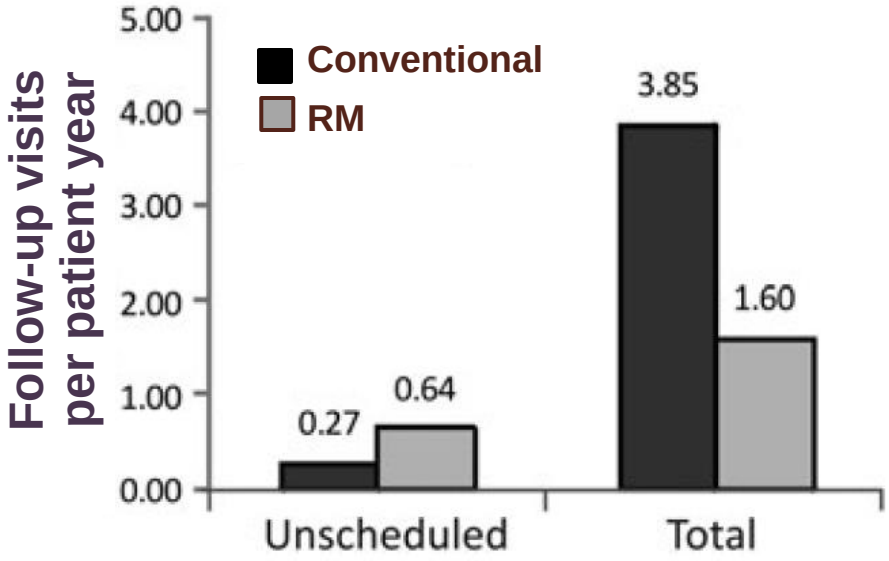
Landolina et al. *Circulation* 2012; 125: 2985-2992
Crossley et al. *JACC* 2011; 57: 1181-1189

Klinische Vorstellungen

RM decreases the total number of in-person follow-up visits without compromising safety

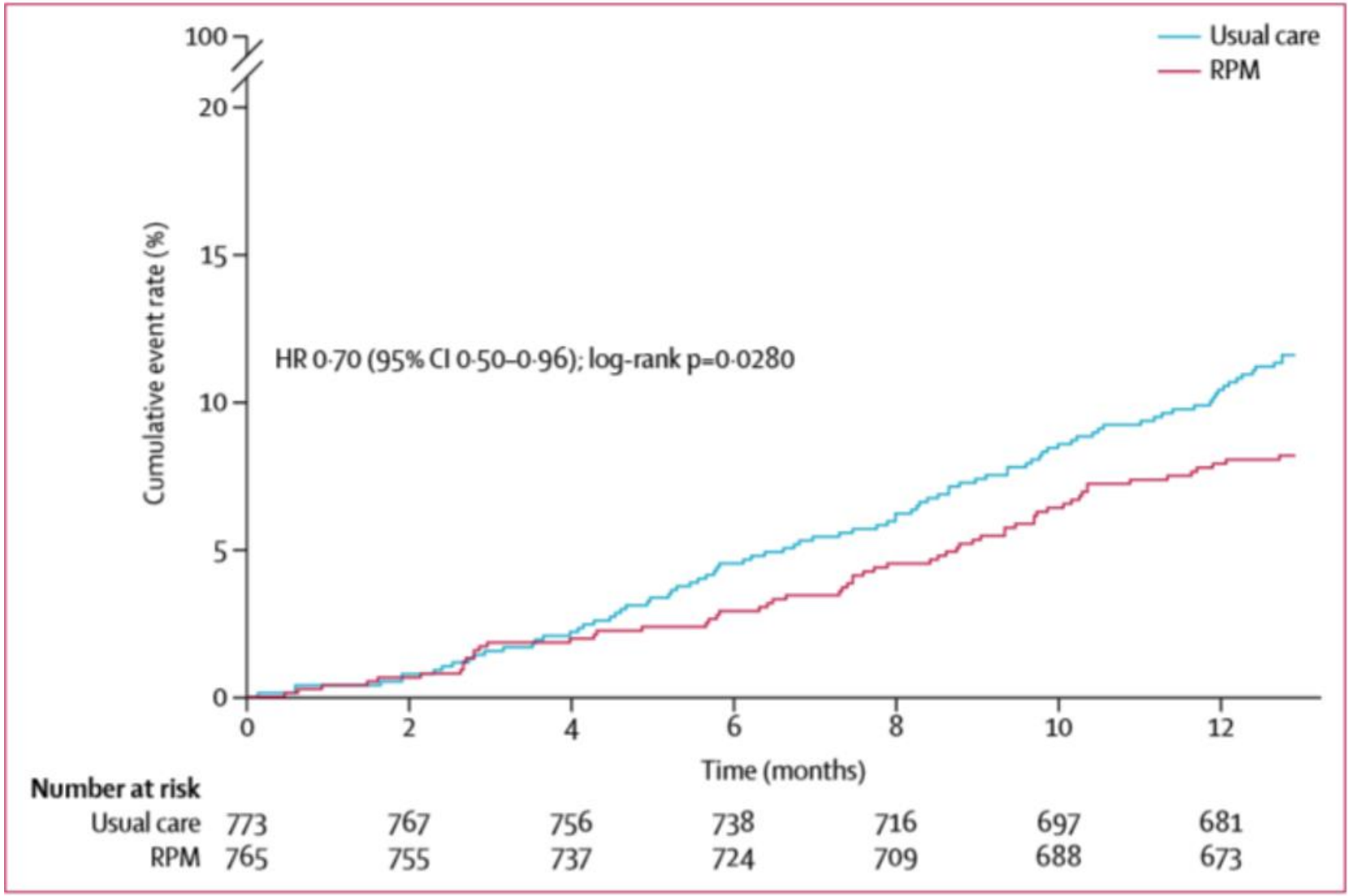
- 58% reduction in REFORM Trial (ICD patients)[1]
- 45% reduction from TRUST trial (ICD patients)[2]
- 56% reduction in COMPAS Trial (pacemaker patients) [3]
- 24% reduction in ECOST Trial (ICD patients) [4]

Mean number of follow-up visits per patient-year[1]



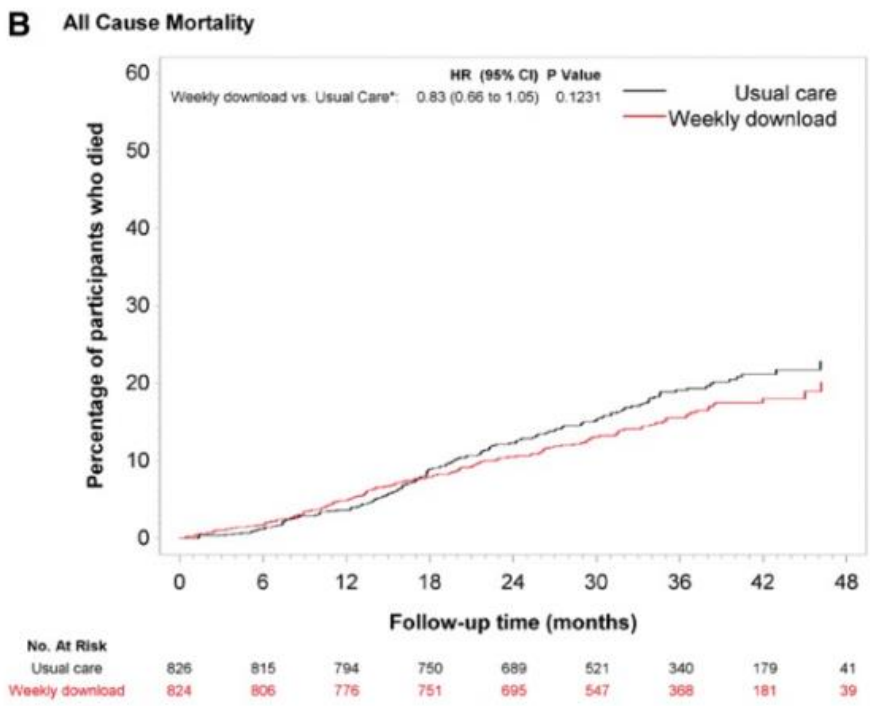
1. Eur Heart J. 2014;35:98–105.
2. Circulation. 2010;122:325-332.
3. Eur Heart J. 2012;33:1105–1111.
4. Eur Heart J. 2013;34: 605–614.

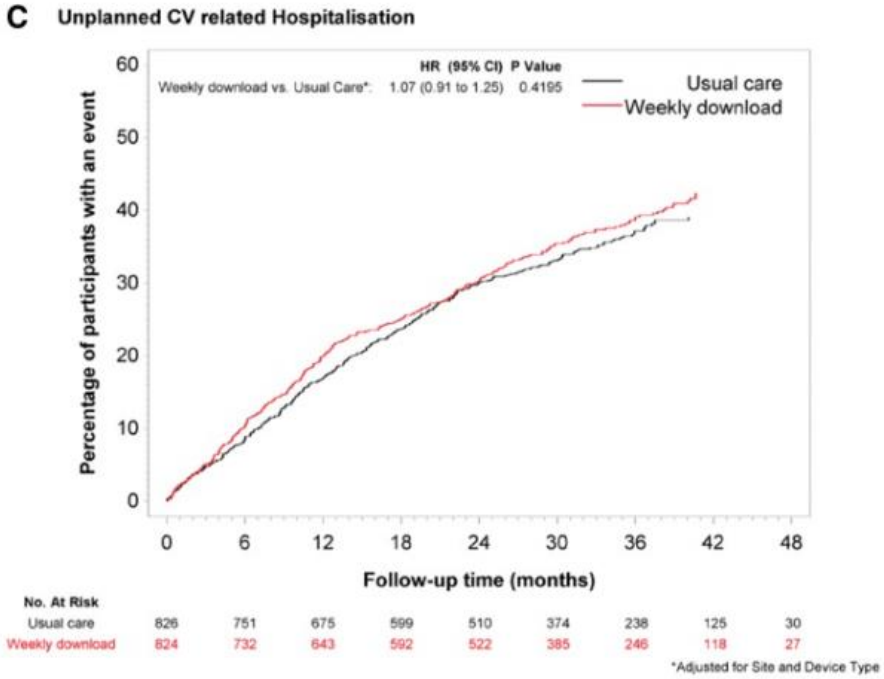
TIM-HF2 Study



Köhler F et al. Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial; Lancet 2018

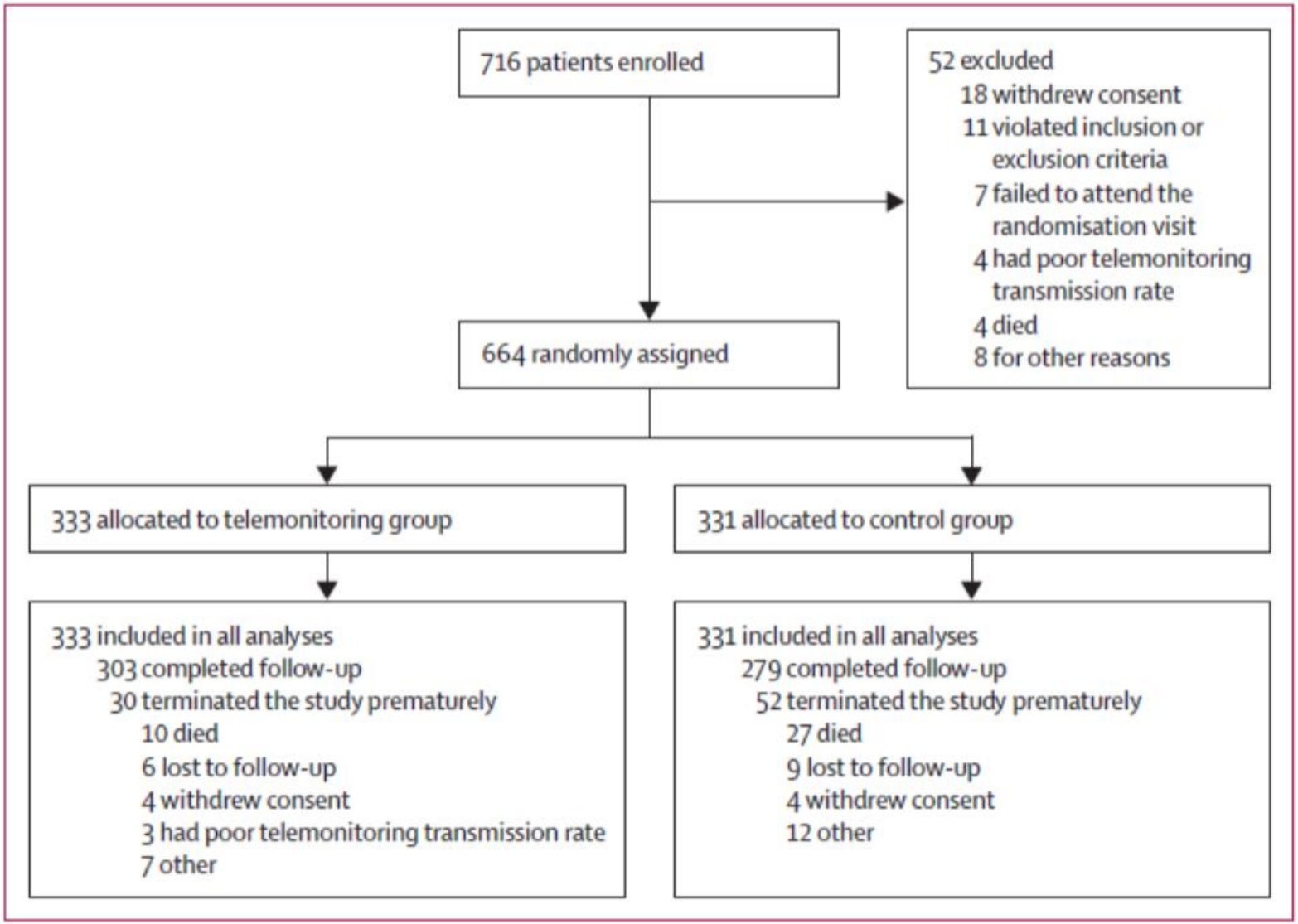
REM-HF Study





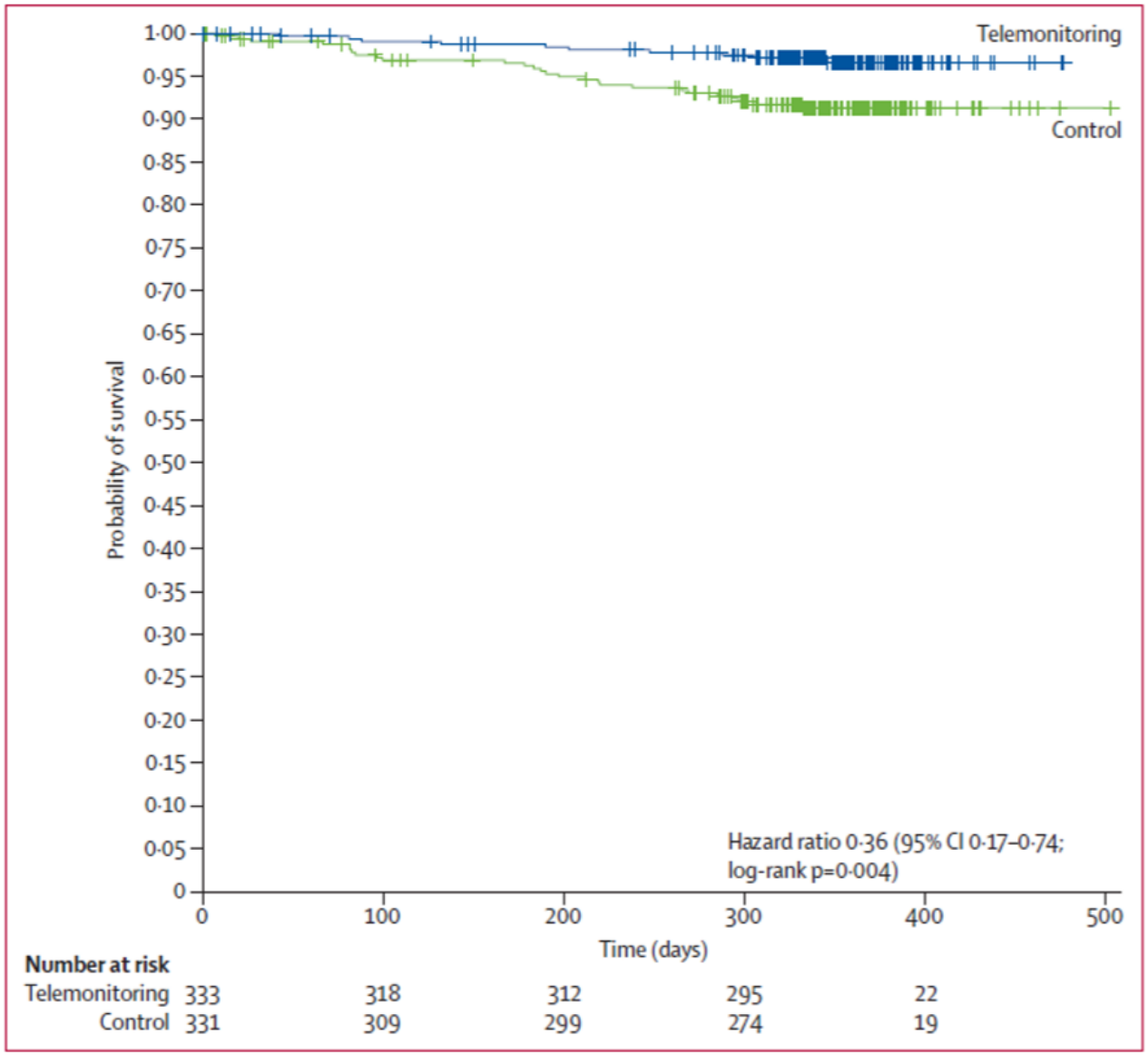
Morgan et al. Eur Heart J 2017

In-Time Study



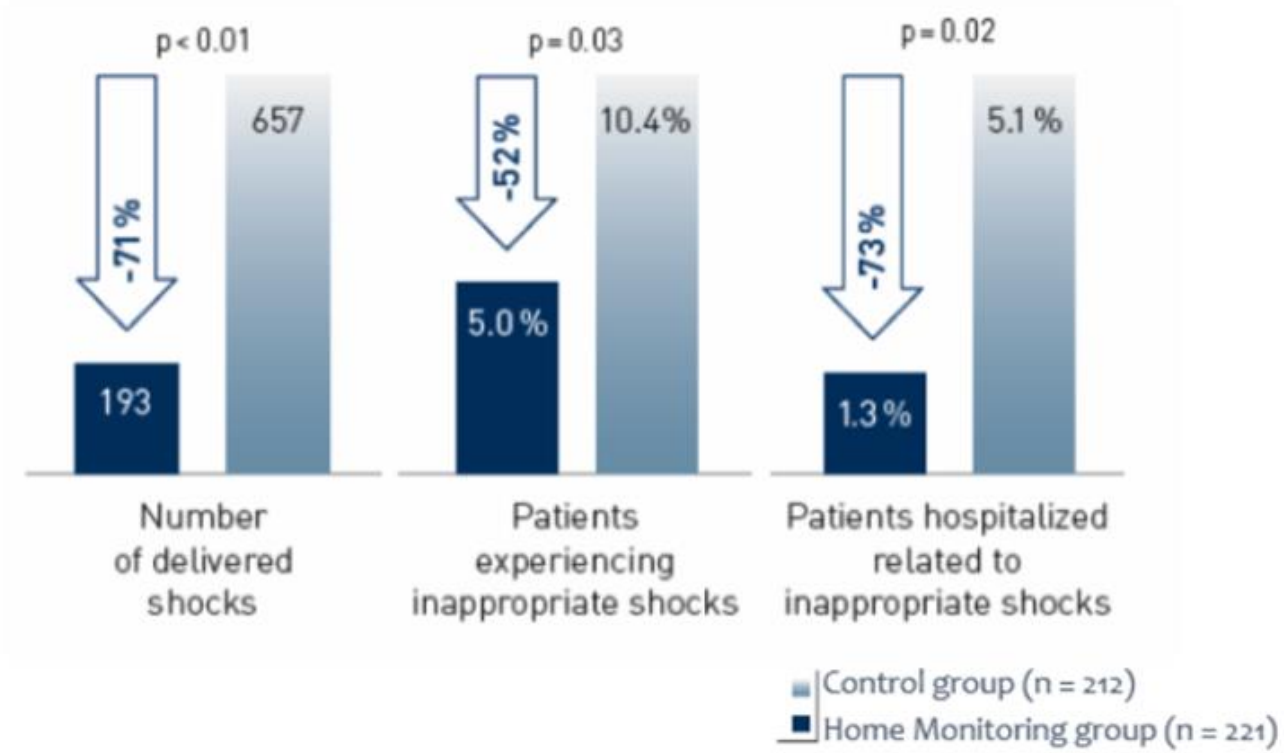
Hindricks et al. Lancet 2014

In-Time Study



Hindricks et al. Lancet 2014

ECOST Study
Reduction of Appropriate and Inappropriate Shocks



Guedon-Moreau et al. Eur Heart J 2012

European Heart Journal (2017) **38**, 1749–1755
doi:10.1093/eurheartj/ehx015

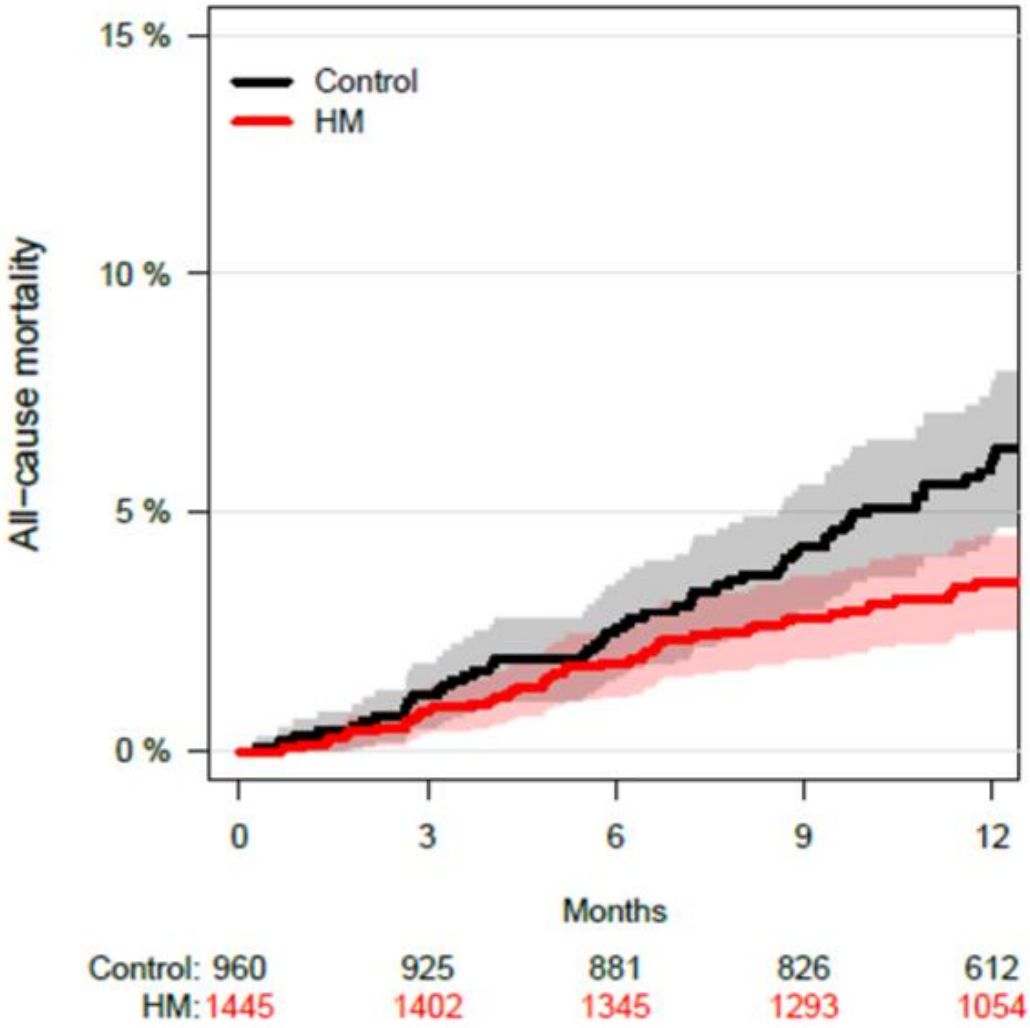
CLINICAL RESEARCH
Arrhythmia/electrophysiology

Daily remote monitoring of implantable cardioverter-defibrillators: insights from the pooled patient-level data from three randomized controlled trials (IN-TIME, ECOST, TRUST)

Gerhard Hindricks[1]*, Niraj Varma[2], Salem Kacet[3], Thorsten Lewalter[4], Peter Søgaard[5], Laurence Guédon-Moreau[3], Jochen Proff[6], Thomas A. Gerds[7], Stefan D. Anker[8], and Christian Torp-Pedersen[9]

	TRUST[3]	ECOST[5]	IN-TIME[12]
No. of centres	102 USA sites	43 French sites	26 German sites, 10 sites elsewhere[a]
Patient eligibility	Class1 indication for ICD, not pacemaker dependent	Indication for ICD, not NYHA class IV	Indication for ICD or CRT-D, heart failure (≥ 3 months), NYHA class II or III, LVEF ≤ 35%
Primary objective	To evaluate safety and efficacy of extended IO intervals	To compare major CVAEs including all-cause death	To compare heart failure outcomes using composite ("Packer") score[b]
Follow-up schedule			
HM group	IO at 3M and 15M. HM replaced IO at 6M, 9M, and 12M	IO at 1-3M, 15M, and 27M. HM replaced IO at 9M and 21M	IO at 12M, and in-between according to hospital routine
Control group	IO every 3M	IO at 1-3M, then every 6M	Same as in the HM group
Blinded endpoint committee	No	Yes	Yes

Meta-Analysis von In-TIME, TRUST und ECOST



p=0.037

Kosteneffizienz?

Einsparungen:

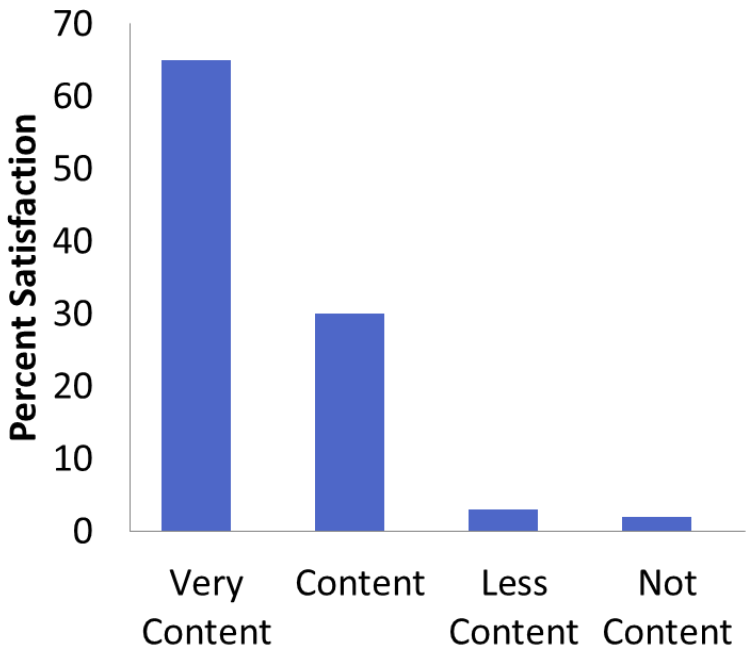
1. Weniger Fahrtkosten
2. Weniger Patientenvorstellungen
3. Erhöhte Effizienz bei Patientenvorstellungen

Patienten Zufriedenheit

Multiple studies have demonstrated high patient satisfaction with RM

- Peterson et al. (ICD/CRT-D patients) [1]
  - 95% of patients followed remotely were content or very content
  -
- Ricci et al. (pacemaker and ICD patients)[2]
  - 95% had a favorable opinion of RM
  - 97% would continue with RM
- Morichelli et al. (ICD/CRT-D patients) [3]
  - 99% of patients had favorable responses to RM
- Raatikainen et al. (ICD patients)[4]
  - >90% of patients thought their RM system was easy to use

Patientenzufriedenheit bei RM[1]



***1. J Interv Card Electrophysiol.* 2012;34:317–324.**
2. Europace. 2010;12:674–679.
3. J Interv Card Electrophysiol. 2014;41:203–209.
4. Europace. 2008;10:1145–1151.

Robuste Evidenz

- Reduced in-hosp visits
  - REFORM
  - TRUST
- As safe
  - REFORM
  - TRUST
  - ECOST
- Increased QofL
  - REFORM
- Reduced shocks
  - ECOST
- Earlier notification
  - TRUST

HRS Guide lines

HRS Remote Monitoring Consensus Statement Recommendations

Device Follow-Up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A
Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.	I	E
It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks postimplantation.	I	E
It may be beneficial to initiate RM within the 2 weeks of CIED implantation.	IIa	C
All patients with an implantable loop recorder with wireless data transfer capability should be enrolled in an RM program, given the daily availability of diagnostic data.	I	E
It is recommended that allied health care professionals responsible for interpreting RM transmissions and who are involved in subsequent patient management decisions have the same qualifications as those performing in-clinic assessments and should ideally possess IBHRE certification for device follow-up or equivalent experience.	I	E
It is recommended that RM programs develop and document appropriate policies and procedures to govern program operations, the roles and responsibilities of those involved in the program, and the expected timelines for providing service.	I	E

CIED = cardiac implantable electronic device; HRS = Heart Rhythm Society; IBHRE = International Board of Heart Rhythm Examiners; IPE = in-person evaluation; RM = remote monitoring.

Device and Disease Management	Class of Recommendation	Level of Evidence
RM should be performed for surveillance of lead function and battery conservation.	I	A
Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	I	E
RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R
RM is useful for the early detection and quantification of atrial fibrillation.	I	A
The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to manage congestive heart failure is currently uncertain.	IIb	C

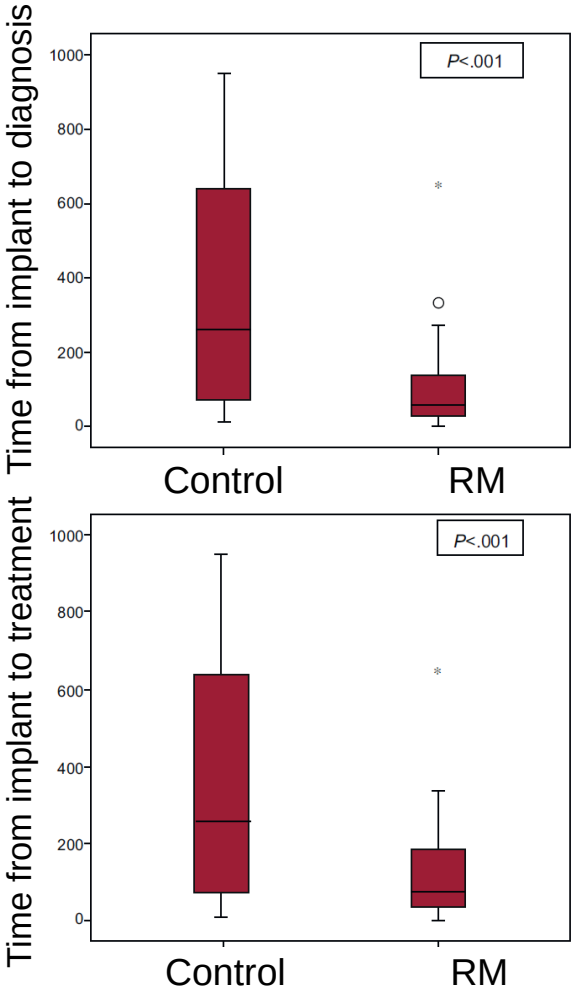
B-R = level of evidence B indicates a moderate level from randomized trials; CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; RM = remote monitoring.

Telemedizin: Diagnostische Devices

ICMs have been shown to:

- Improve diagnostic yield in unexplained syncope
  - 33-78% improvement over conventional methods
- Improve detection of asymptomatic and intermittent AF
  - Cryptogenic stroke
    - Use of ICM provides superior diagnostic yield than conventional monitoring
  - Post-ablation
    - Improved detection of AF

Synkope:
Schnellere Diagnosestellung und Therapiebeginn



- Velu et al. (patients with unexplained syncope)[1]
  - 47% reduction in mean time from ICM implant to diagnosis
- Drak-Hernandez et al. (patients with unexplained syncope or palpitations)[2]
  - RM increased:
    - The time from implant to diagnosis by 78%
    - The time from implant to treatment by 72%
- Furukawa et al. (patients with unexplained syncope or palpitations)[3]
  - RM decreased the mean time to first relevant ECG by ~71 days

1. *Europace.* 2010;4 (suppl 4):iv22-iv27.
2. *Rev Esp Cardiol.* 2013;66(12):943–948.
3. Europace. 2011;13:431–437.

ESC European Society of Cardiology
European Heart Journal (2018) **00**, 1–69
doi:10.1093/eurheartj/ehy037

2018 ESC Guidelines for the diagnosis and management of syncope

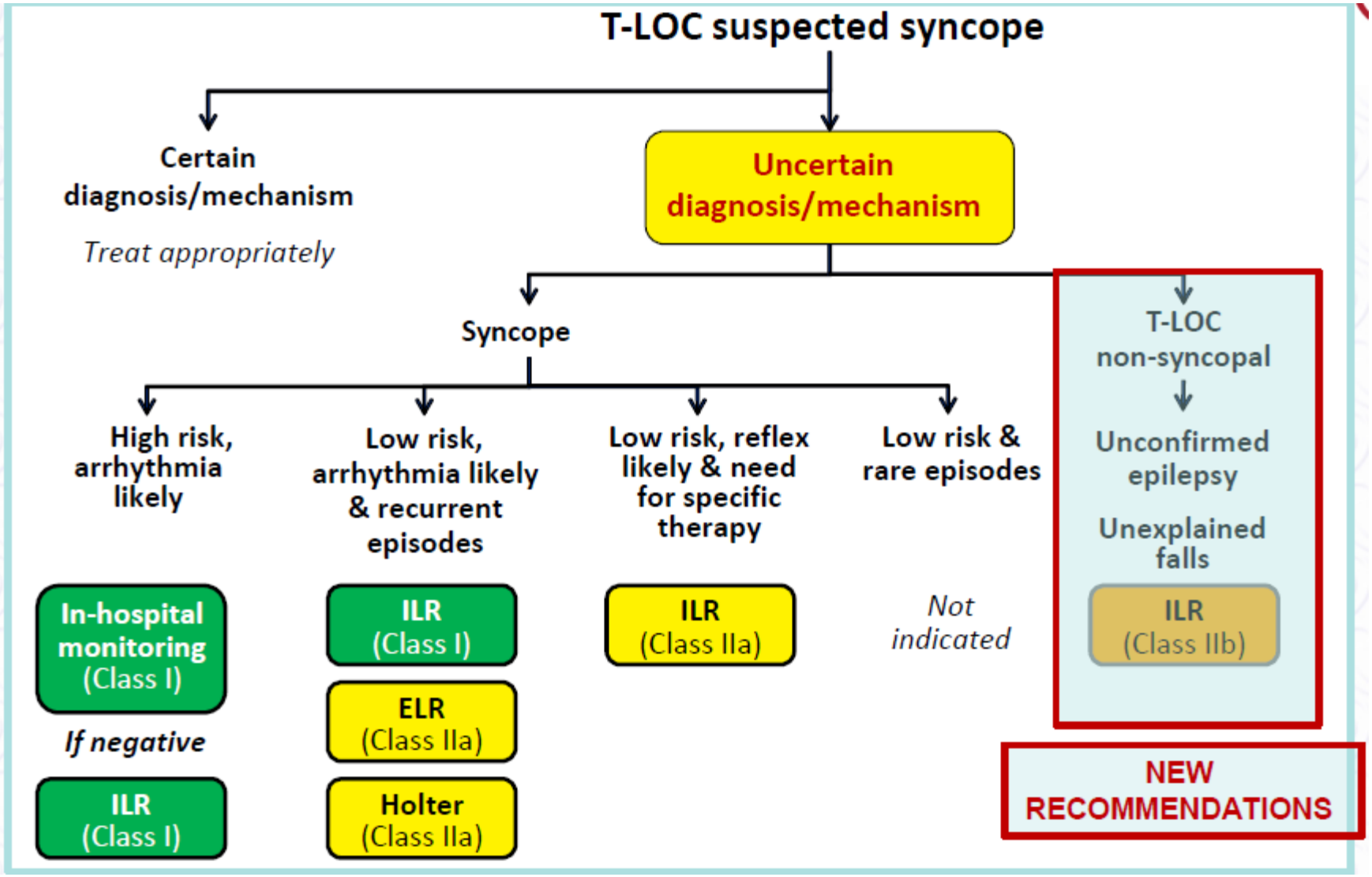
The Task Force for the diagnosis and management of syncope of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA)

Endorsed by: European Academy of Neurology (EAN), European Federation of Autonomic Societies (EFAS), European Federation of Internal Medicine (EFIM), European Union Geriatric Medicine Society (EUGMS), European Society of Emergency Medicine (EuSEM)

Authors/Task Force Members: Michele Brignole* (Chairperson) (Italy), Angel Moya* (Co-chairperson) (Spain), Frederik J. de Lange (The Netherlands), Jean-Claude Deharo (France), Perry M. Elliott (UK), Alessandra Fanciulli (Austria), Artur Fedorowski (Sweden), Raffaello Furlan (Italy), Rose Anne Kenny (Ireland), Alfonso Martín (Spain), Vincent Probst (France), Matthew J. Reed (UK), Ciara P. Rice (Ireland), Richard Sutton (Monaco), Andrea Ungar (Italy), and J. Gert van Dijk (The Netherlands)

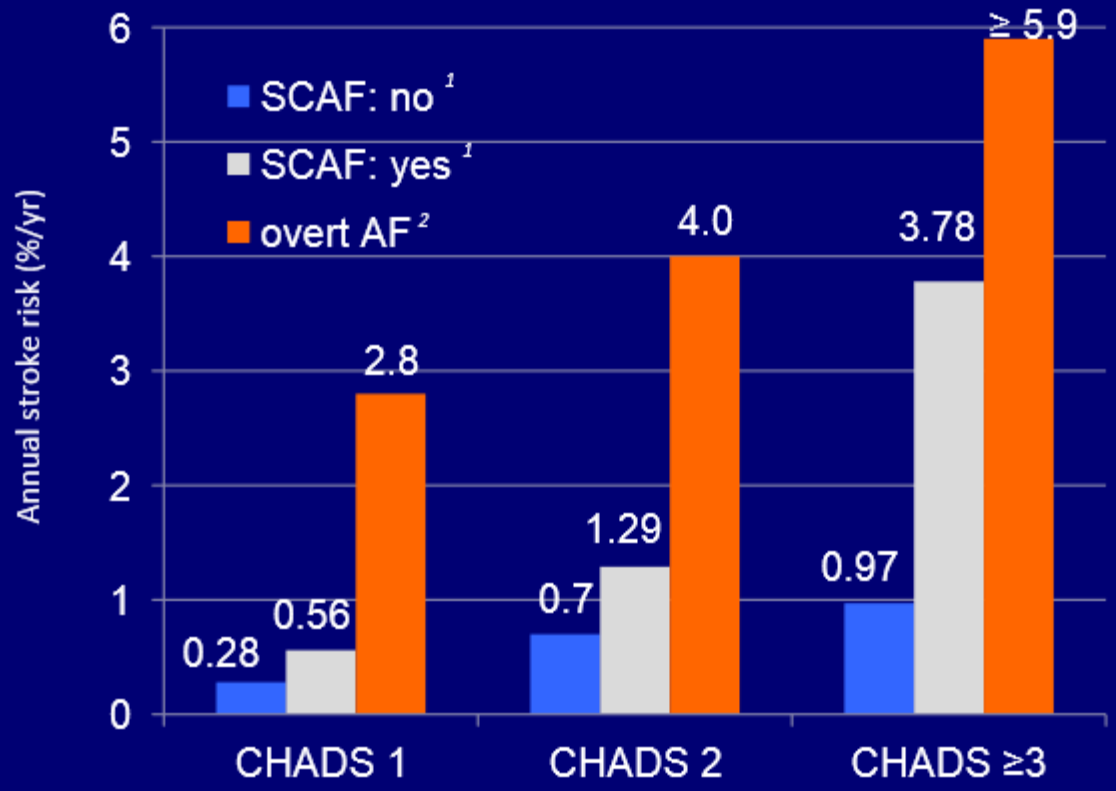
ECG Monitoring Indications



ESC Guidelines 2018

Kontinuierliches AF Monitoring

Stroke Risk for SCAF is Lower than AF



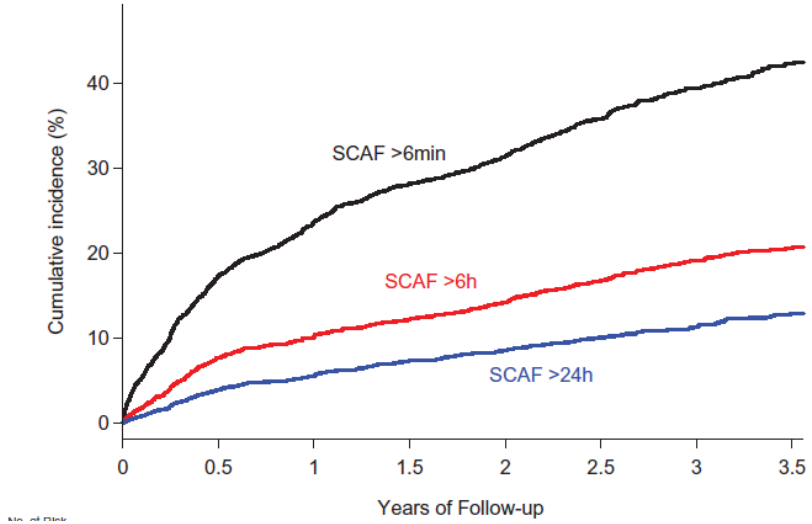
Slide courtesy of Jeff Healey

[1]Healey JS et al. N Engl J Med. 2012;366:120–9
[2]Gage BF et al. JAMA. 2001;285:2864–70

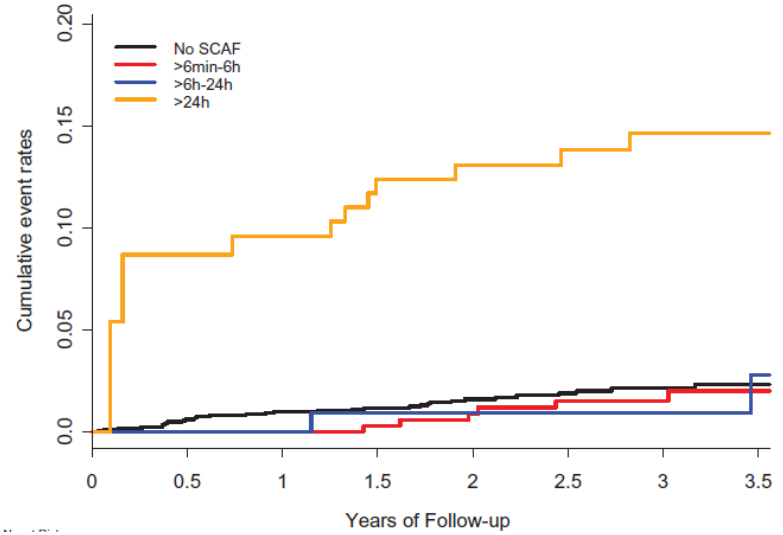
ASSERT: AF Duration and Stroke

- 2,580 pts. with a history of hypertension, ≥65 years, no history of AF and not on OAC received a DDD / ICD (ASSERT)
- Subclinical AF (SCAF) longer than 24h was associated with an increased risk of ischemic stroke / systemic embolism

Cumulative incidence of SCAF



Risk of ischemic stroke or systemic embolism



Van Gelder I. *European Heart Journal* 2017; 38: 1339–1344

Atrial fibrillation requires diagnosis by ECG I

ESC
European Society of Cardiology

The diagnosis of AF requires rhythm documentation using an electrocardiogram (ECG) showing the typical pattern of AF: Absolutely irregular RR intervals and no discernible, distinct P waves. ECG-documented AF was the entry criterion in trials forming the evidence for these guidelines. By accepted convention, an episode lasting at least 30 s is diagnostic.

Vorteile der Telemedizin:

EVIDENZ VON IMPLANTIERTEN DIAGNOSTISCHEN DEVICES

1. RM: zusätzliches diagnostisches Tool bei Synkopenabklärung

2. RM: Ggf. zusätzliches diagnostisches Tool bei Vorhofflimmern Diagnostik

Vorteile der Telemedizin:

EVIDENZ VON IMPLANTIERTEN THERAPEUTISCHEN DEVICES

1. Frühere Detektion und Evaluation klinischer und device-bezogener Events
2. Weniger Patientenvorstellungen bei gleicher Sicherheit
3. Weniger Hospitalisationen
4. Kürzerer Spitalaufenthalt
5. Bessere Kosteneffizienz
6. Hohe Patientenzufriedenheit
7. Geringere Mortalität im follow-up

Telemedizin: Risiken und offene Fragen

1. Cave: Pseudosicherheit!

2. Datenanalyse allein verbessert nichts!

   → entscheidend ist die Umsetzung in therapeutische Konsequenzen

3. Verschiedene Systeme verschiedener Hersteller

4. Bisher keine Schnittstelle zwischen RM und Spitalsystemen

5. Datenexplosion in der Zukunft

Telemedizin
Zukunftsperspektive

1. Telemedizin hat bereits den medizinischen Alltag verändert

2. Telemedizin wird ein wichtiger Teil der Medizin der Zukunft sein

3. Künstliche Intelligenz wird bei der Datenverarbeitung eine Rolle spielen?!

Patientenmanagement erheblich komplexer als Devicemonitoring!