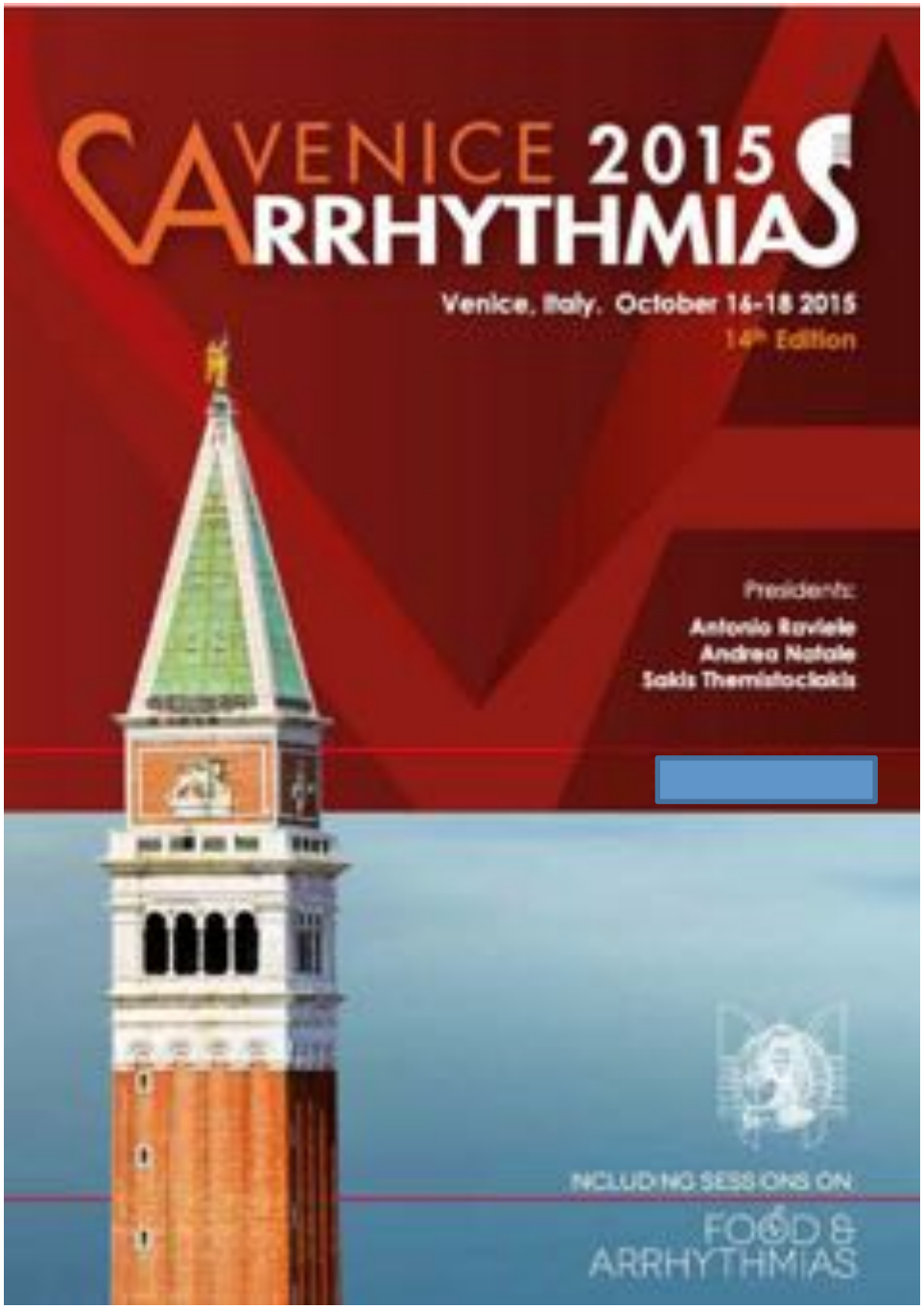
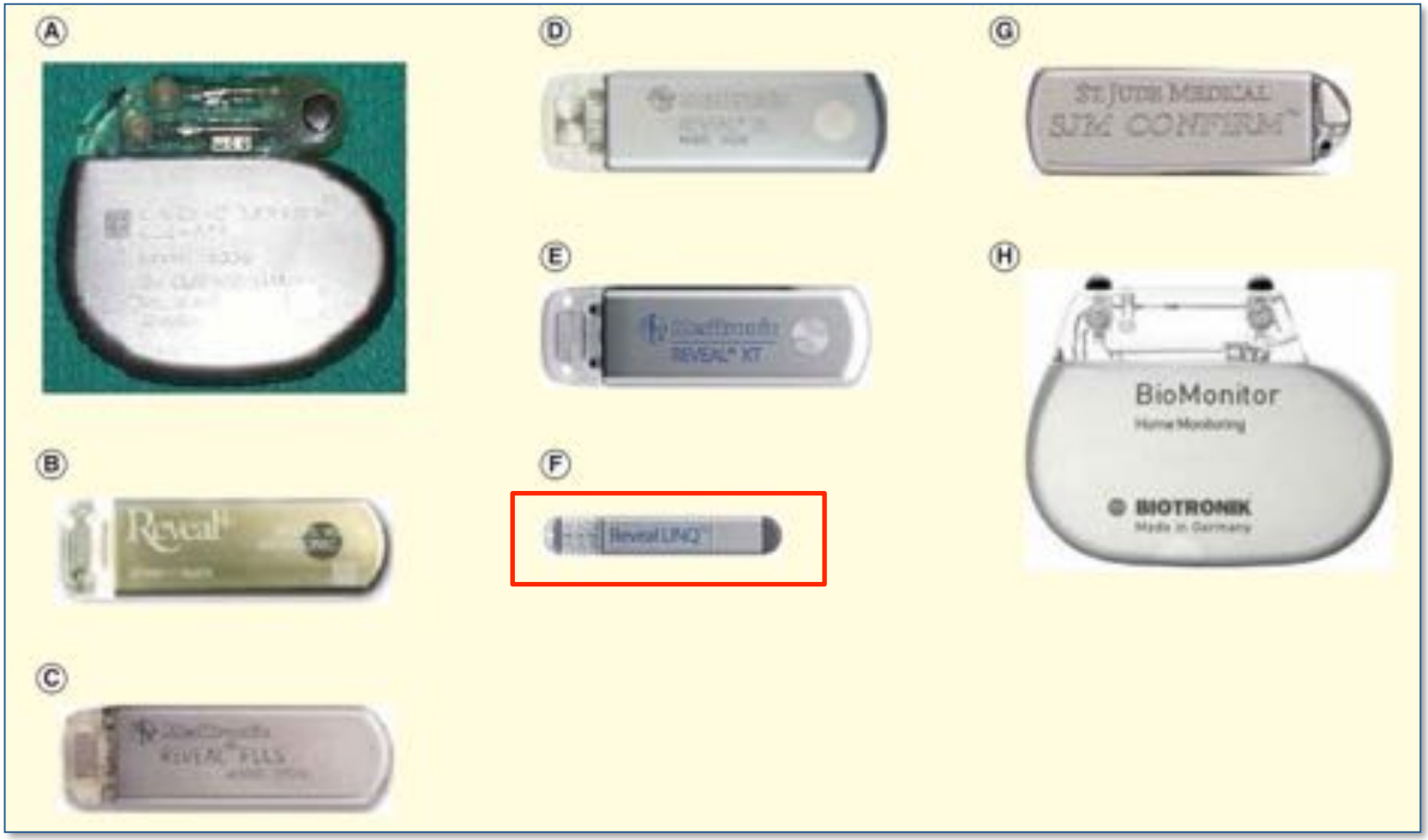


The « injectable » Loop Recorder

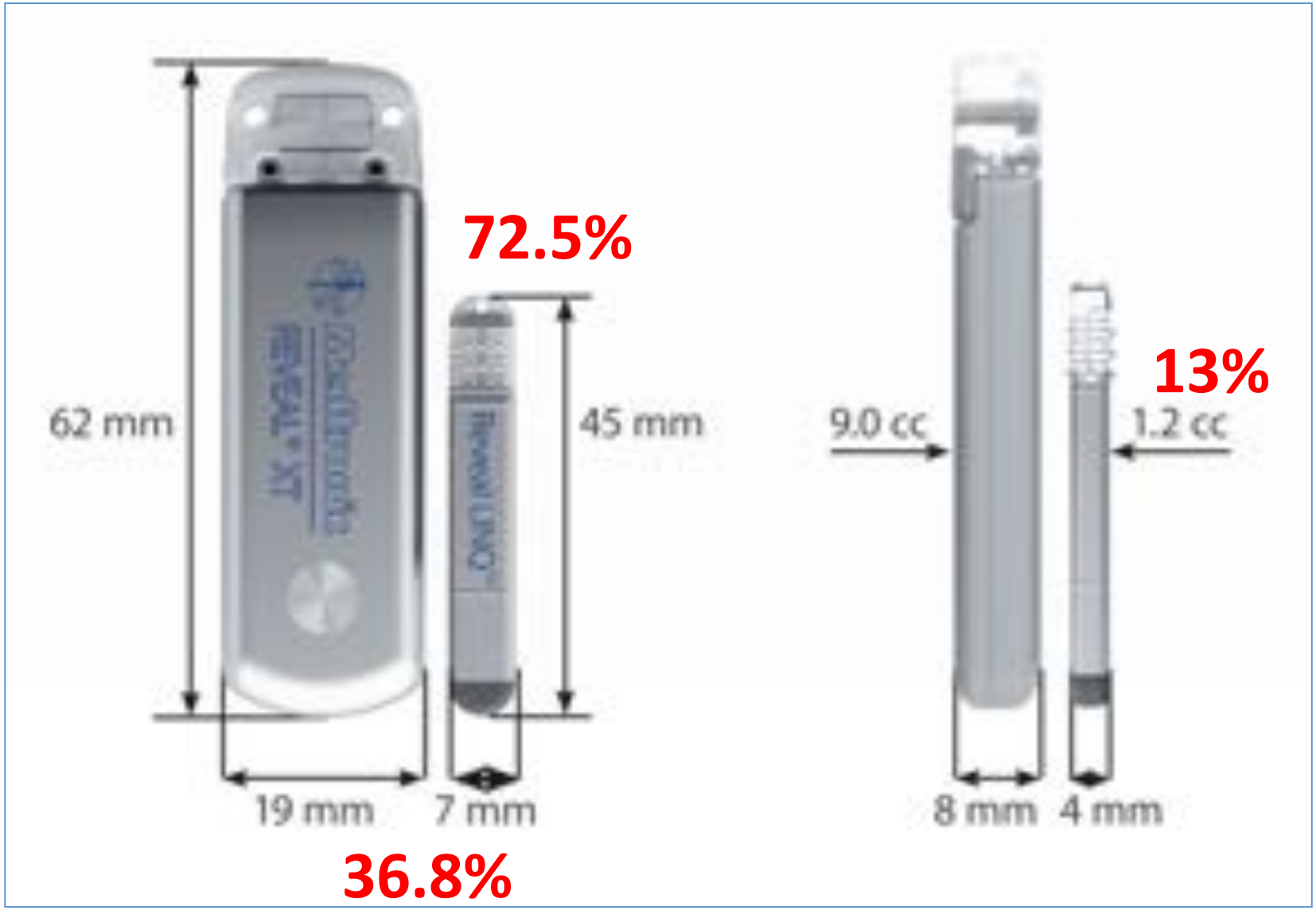
New indications for continuous monitoring

JC Deharo, MD, FESC
Marseilles, France

Aix-Marseille université
Assistance Publique Hôpitaux de Marseille



Tomson & Passman, Expert Rev Med devices 2014



Adapted from Medtronic slide set

Name (brand)	Size (mm)	Battery life (years)	Memory capacity (min)	MRI conditional	Automatic arrhythmia detection	Remote monitoring	Other diagnostic features
Reveal™ (Medtronic, Inc., Minneapolis, MN, USA)	19 × 61 × 8	1.2	21	No	None	No	
Reveal Plus™ (Medtronic)	19 × 61 × 8	1.2	21	No	Asystole, bradycardia, tachycardia	No	
Reveal DX™ (Medtronic)	19 × 61 × 8	3	49	Yes	Asystole, bradycardia, two tachycardia zones	Yes	
Reveal XT™ (Medtronic)	19 × 61 × 8	3	49	Yes	Asystole, bradycardia, two tachycardia zones	Yes	Atrial fibrillation detection algorithms using Lorenz plots
Reveal LINQ™ (Medtronic)	7 × 45 × 4	3	59	Yes	Asystole, bradycardia, two tachycardia zones	Yes	Improved atrial fibrillation algorithms with 'P-sense' to reduce false positives
Confirm (St. Jude Medical, Inc., St. Paul, MN, USA)	18 × 56 × 8	3	48	Yes	Asystole, bradycardia, tachycardia	Yes	Rate based atrial fibrillation detection (in Europe only)
Biomonitor (Biotronik SE & Co. KG, Berlin, Germany) (Available in Europe only)	50 × 60 × 8 (approximate)	6.4	36	Yes	Asystole, bradycardia, tachycardia	Yes	Atrial fibrillation detection algorithms

Tomson & Passman, Expert Rev Med devices 2014

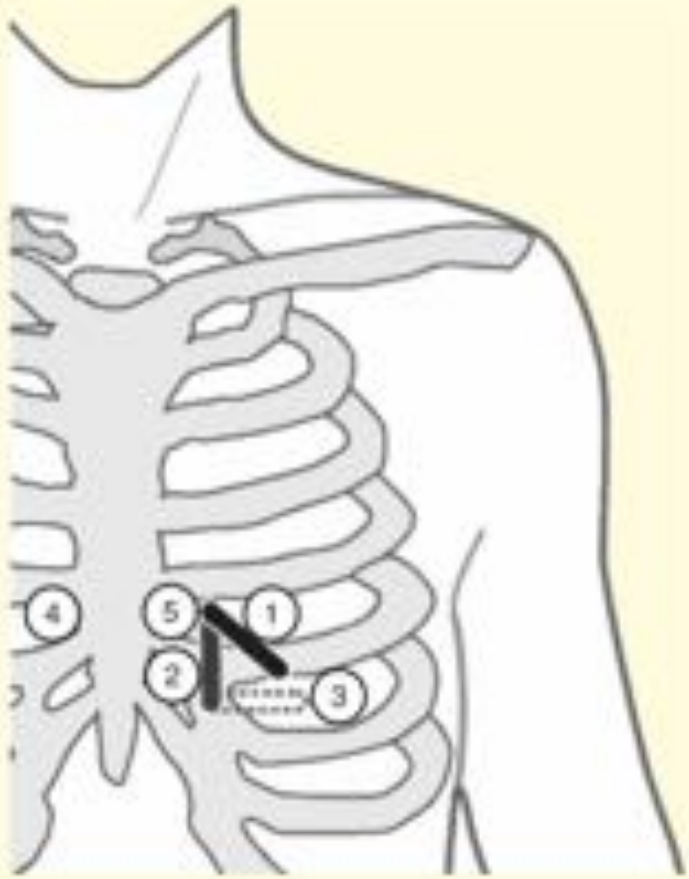
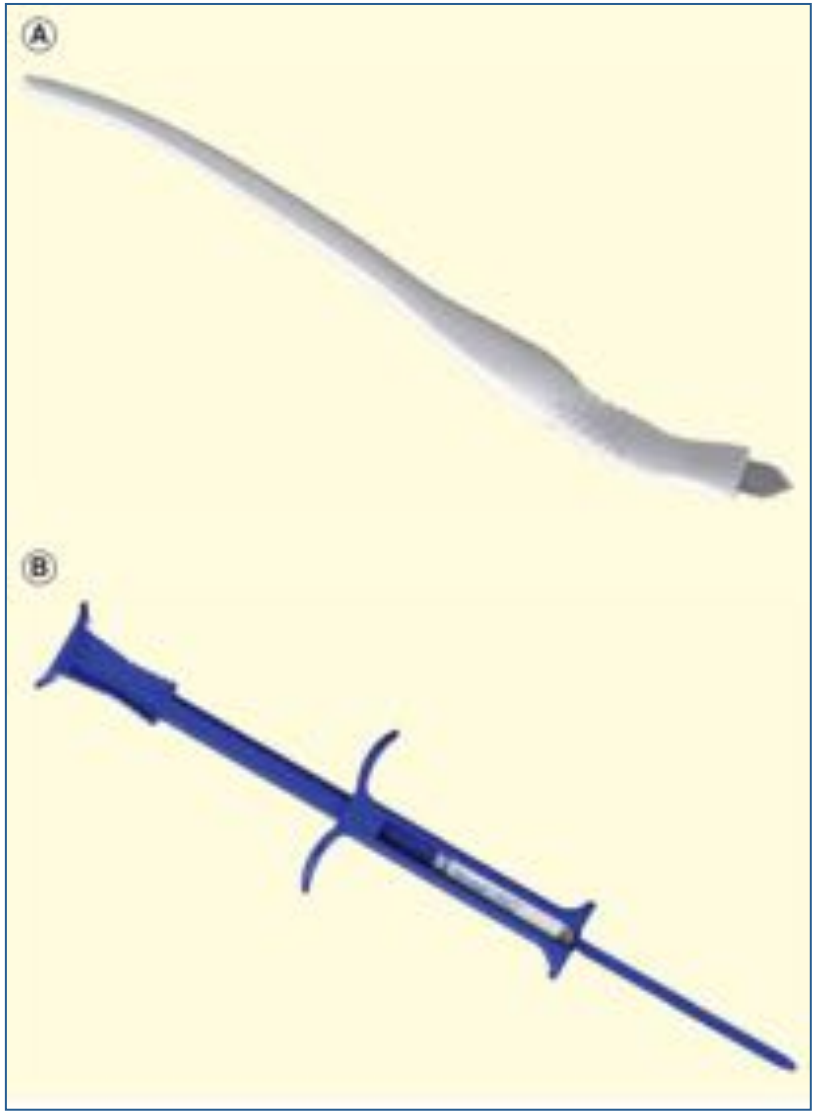
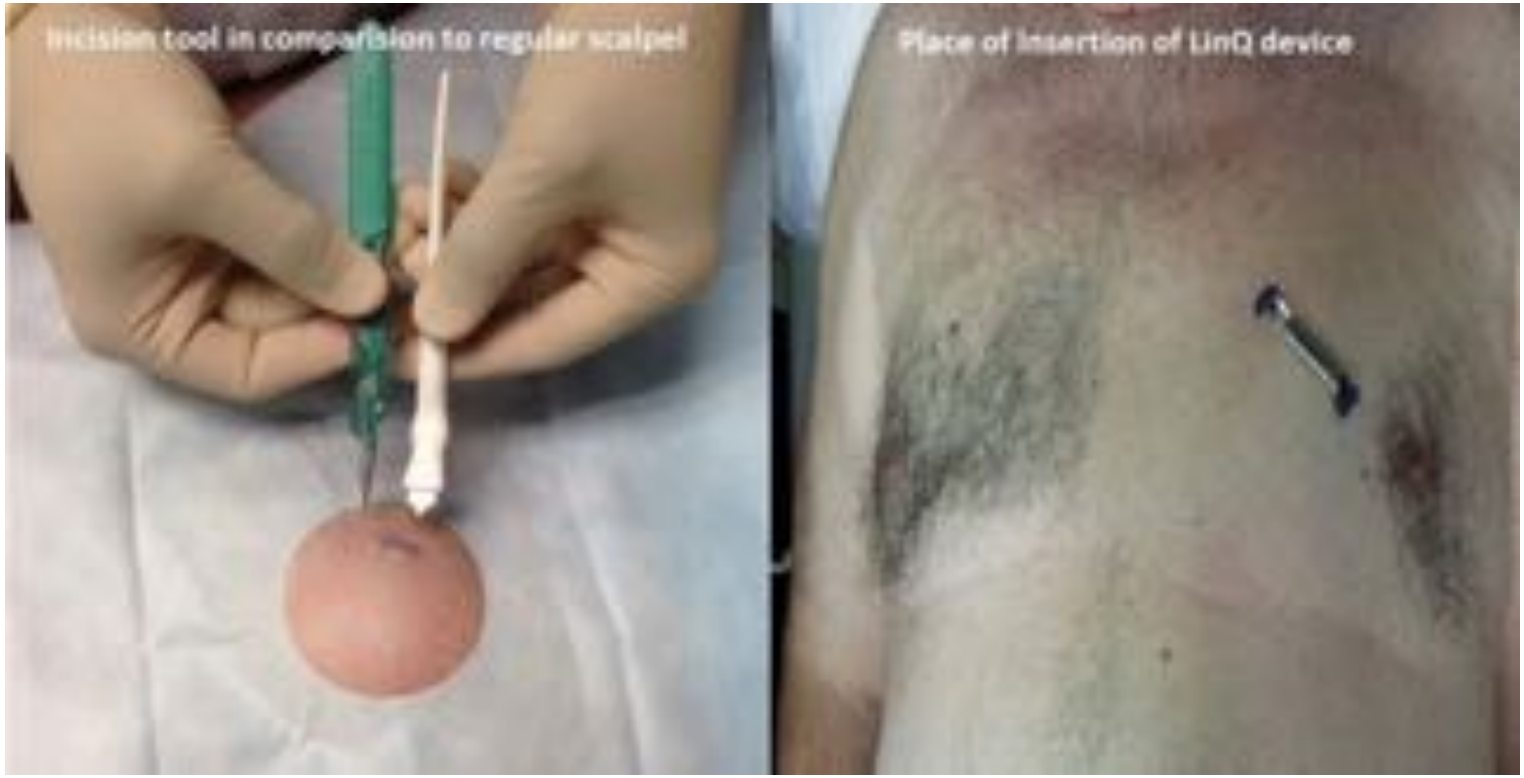


Figure 4. Potential insertion locations for the Reveal LINQ™. Position 1 is best. Position 2 is good. Position 3 is an optional inframammary fold location. Position 4 and 5 are the V1 and V2 ECG electrode locations, respectively. Positions 1 and 2 do not require ECG pre-screening for R-wave amplitude.



Tomson & Passman, Expert Rev Med devices 2014



Gunda et al., Int J Cardiol, 2015

Gunda et al., Int J Cardiol, 2015

Tomson & Passman, Expert Rev Med devices 2014

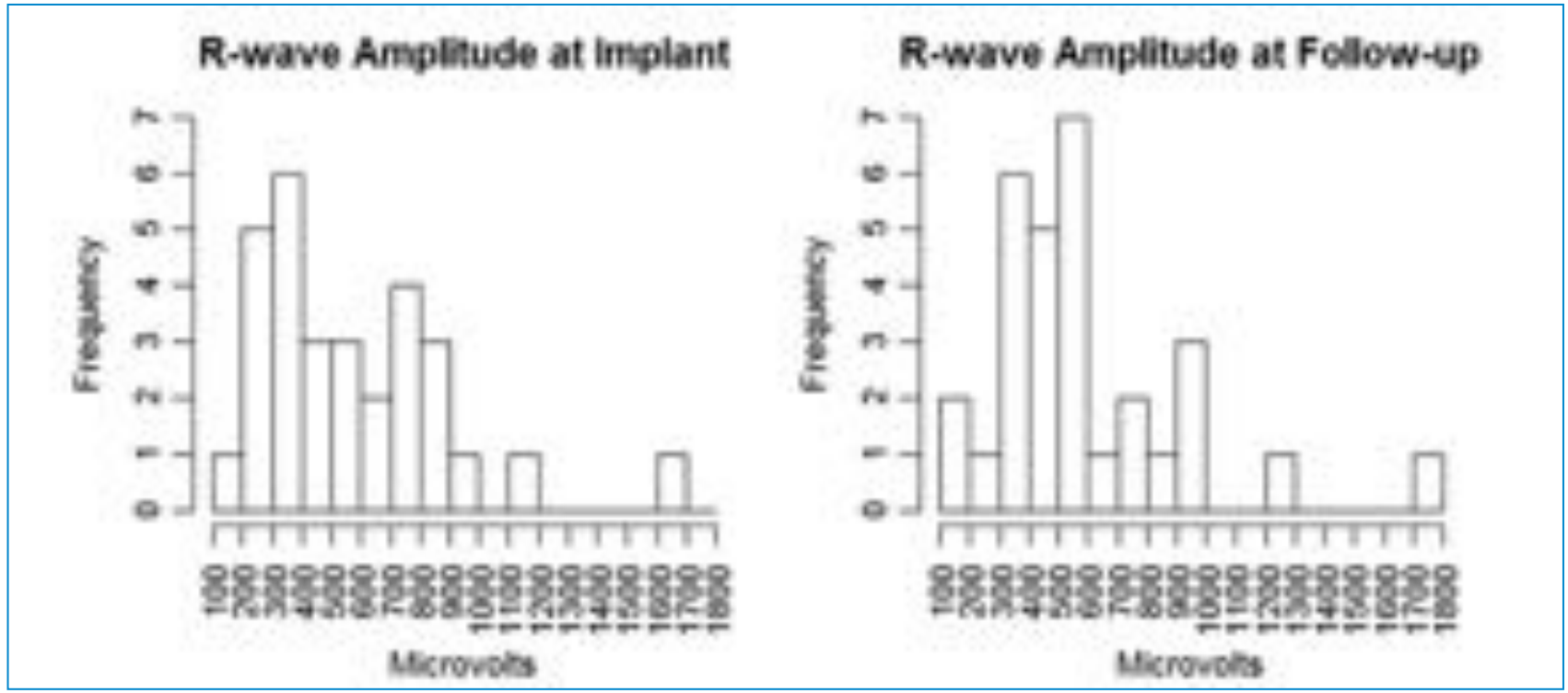
Aix*Marseille université

Assistance Publique Hôpitaux de Marseille

Miniaturized Reveal LINQ insertable cardiac monitoring system: First-in-human experience

Helmut Pürerfellner, MD, FHRS,* Prashanthan Sanders, MBBS, PhD, FHRS,† Evgeny Pokushalov, MD,‡ Marco Di Bacco, PharmD,§ Tracy Bergemann, PhD,‖ Lukas R.C. Dekker, MD, PhD,¶ for the Reveal LINQ Usability Study Investigators

N = 30 pts
1-month FU



Heart Rhythm 2015

«Suspicion» «Proof»

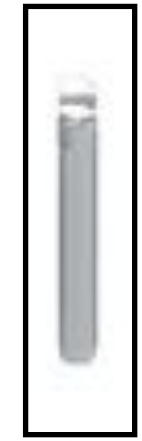
1970 1980 1990 2000

Clinical Evaluation + EKG

EPS Holter monitoring

1986 HUT

1995 Implantable loop recorders



Unexplained Syncope 60 %

Unexplained Syncope 20 %

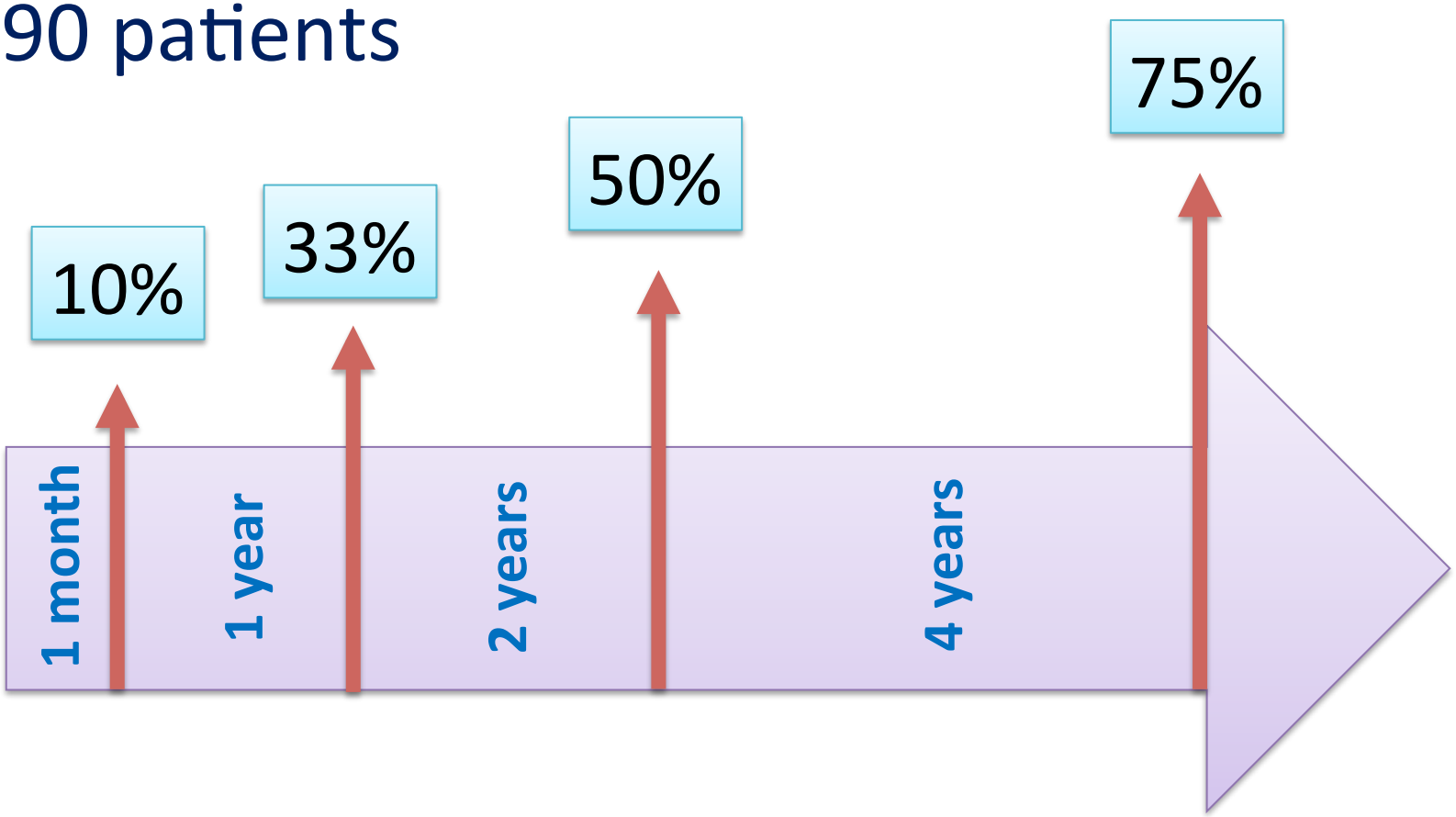
Recommendations: Indications for ILR in patients with syncope

Clinical situation	*Class*	*Level*
• In an **early phase** of evaluation of patients with recurrent syncope of uncertain origin who have: – absence of high-risk criteria that require immediate hospitalization or intensive evaluation, *and* – a likely recurrence within battery longevity of the device	I	B
• In **high-risk** patients in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to specific treatment	I	B
• ILR may be indicated to assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain **neurally mediated syncope** presenting with frequent or traumatic syncopal episodes	IIa	B
• ILR may be indicated in patients with **T-LOC of uncertain syncopal origin** in order to definitely exclude an arrhythmic mechanism	IIb	B

Cumulative probability of syncope recurrence

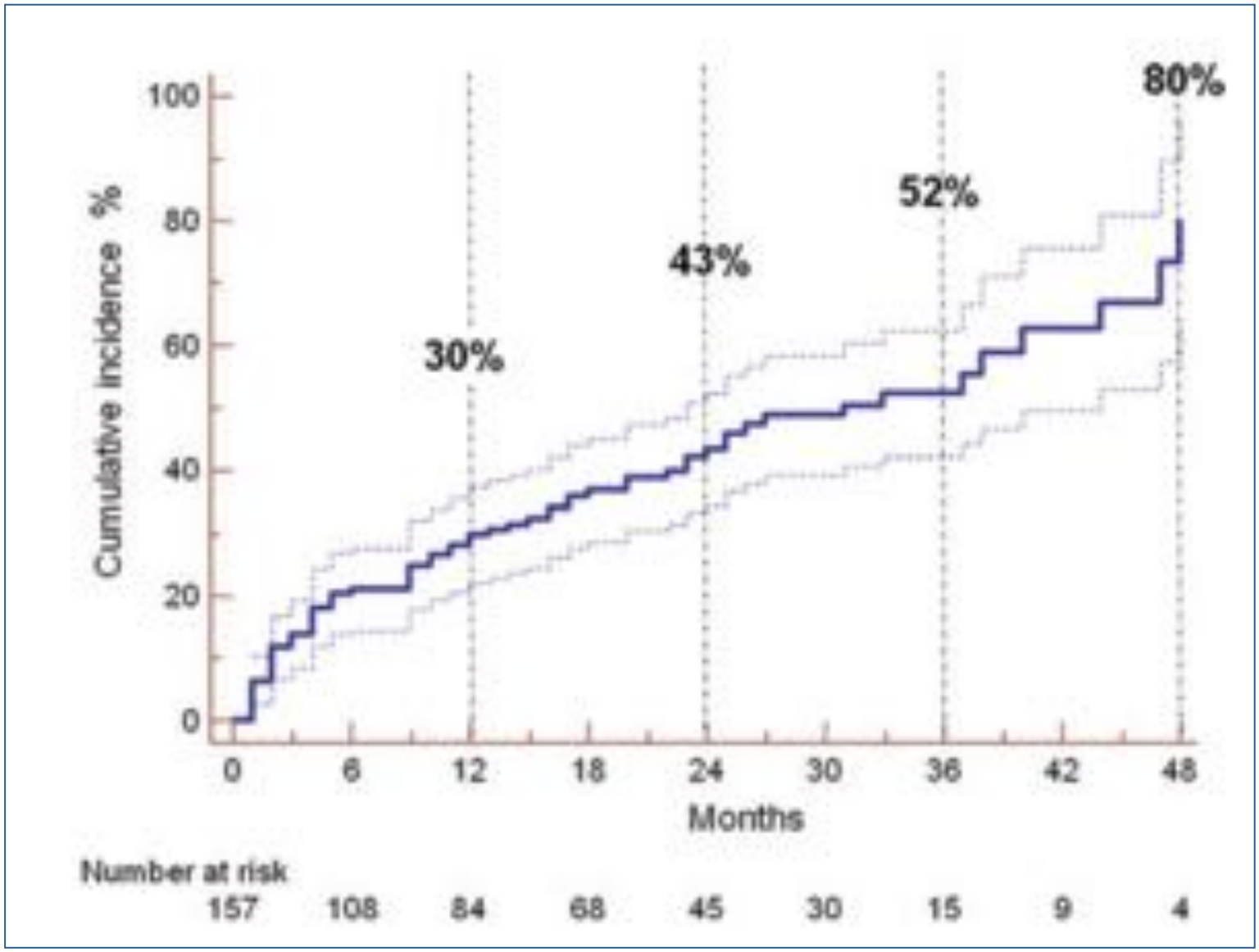
Pooled data from ISSUE 1 and ISSUE 2 studies

N = 590 patients



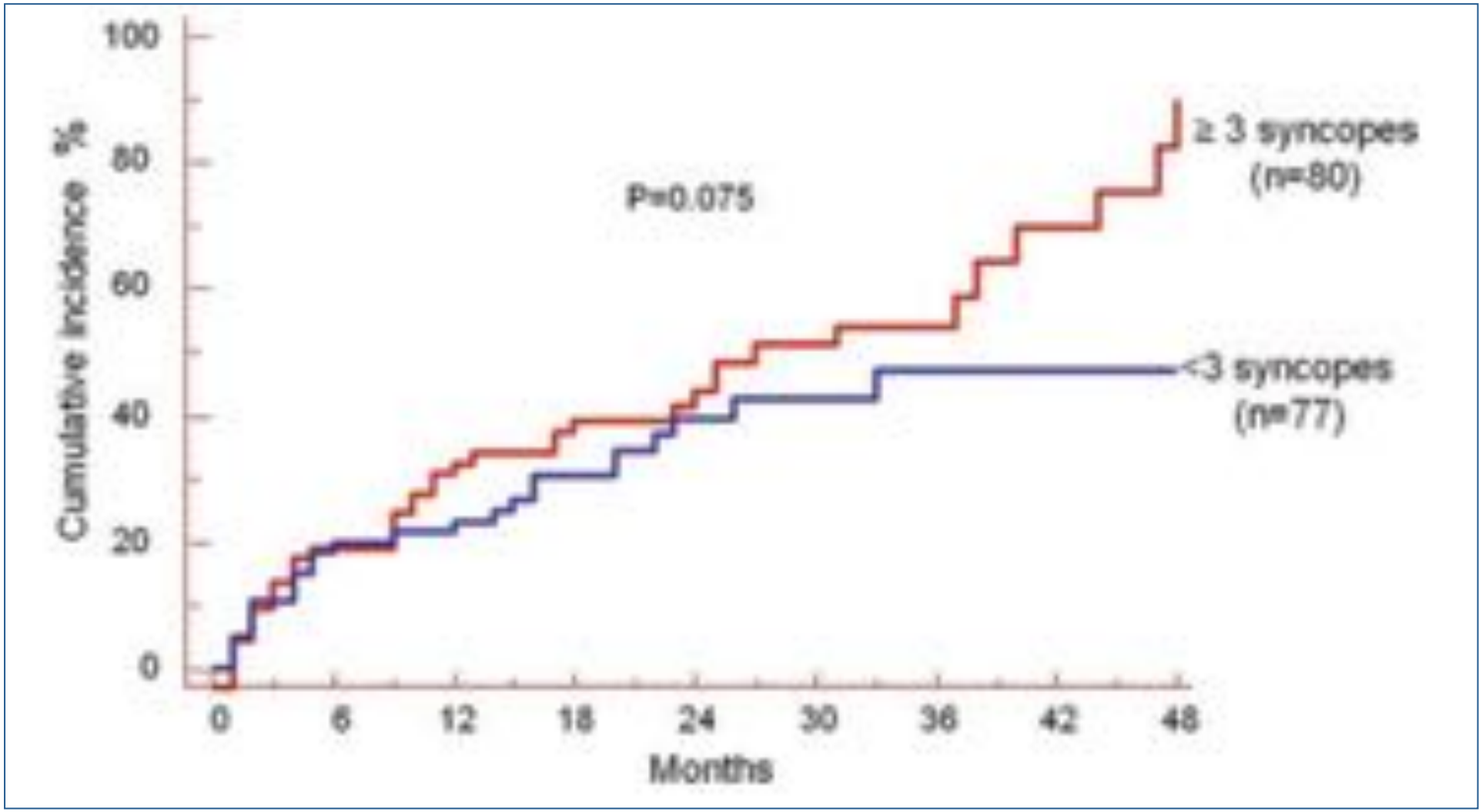
from Brignole M, unpublished data, with permission

Very prolonged observation with ILR



Furukawa T et al, JCE 2011

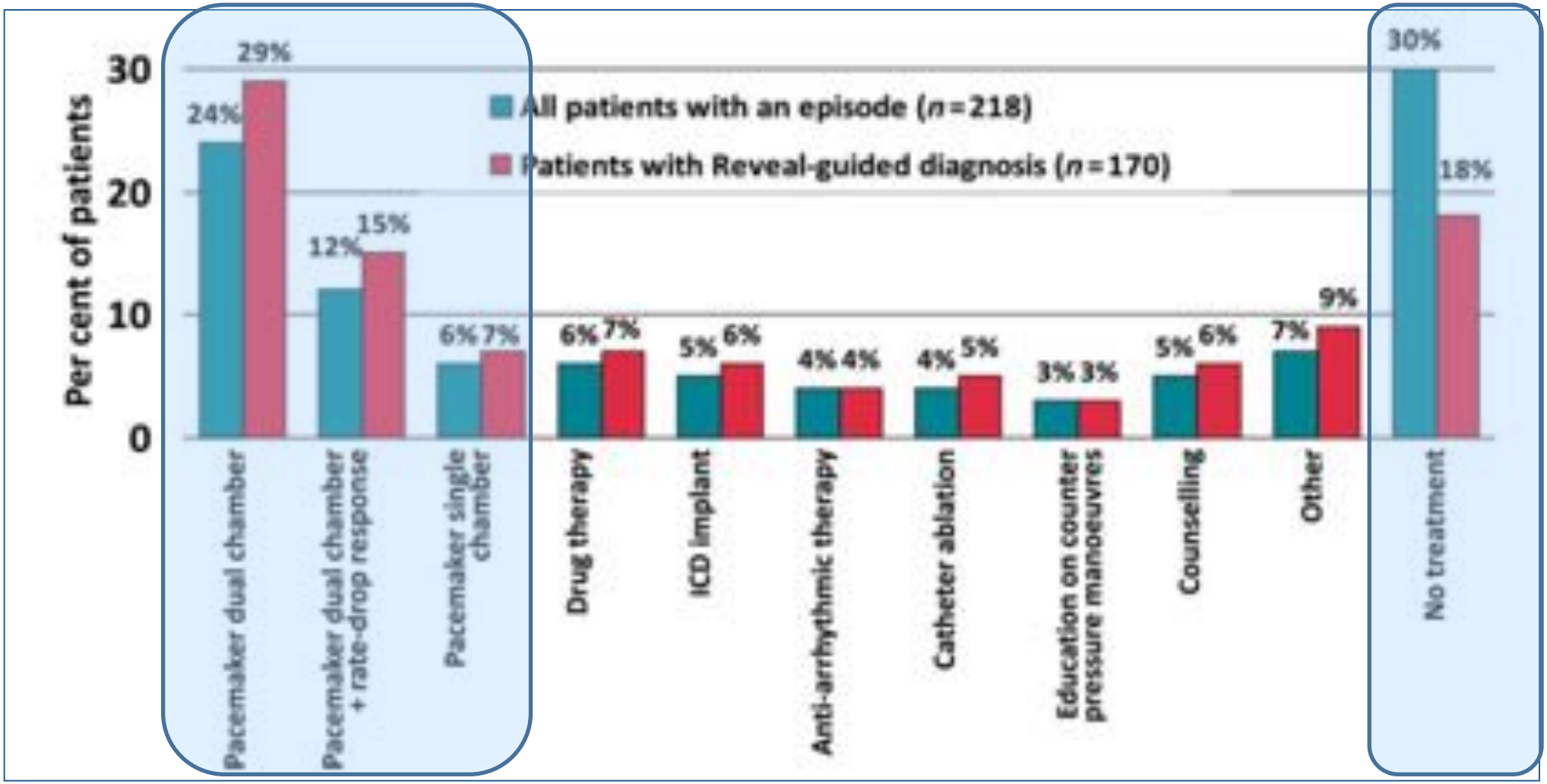
Very prolonged observation with ILR



Furukawa T et al, JCE 2011

The PICTURE study: « real world »

Treatment decisions



Edvardsson N et al, Europace 2011

Indications for ILR

from Brignole M, with permission

Class I indications (unexplained syncope)

Observed incidence:
30 per million inhabitants per year (CI 23-39)

Estimated incidence:
118 per million inhabitants per year (CI 103-134).

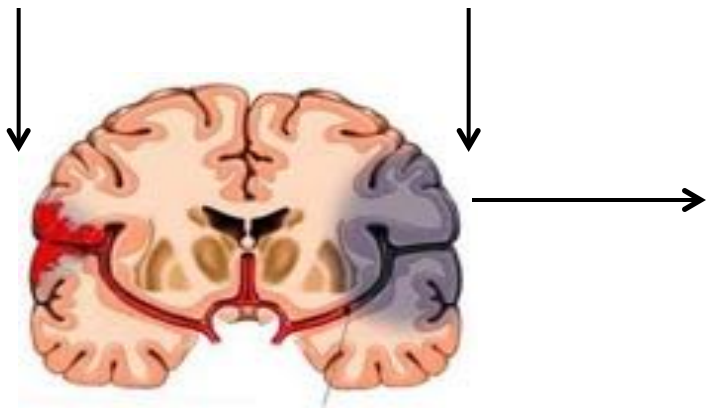
Vitale et al. Europace 2010 ; 12, 1475–1479

Stroke Etiologies

The Challenge of Cryptogenic Stroke

Hemorragic (15%)

Ischemic (85%)



Atherothrombotic (25-30%)

Stenotic artery feeding area of infarction

Cardioembolic (20%)

A thrombus or other material dislodges from the heart or aortic arch

Lacunar/Small Vessel (15-20%)

Small, deep infarct

Other/Uncommon (5-10%)

Cryptogenic (25-30%)

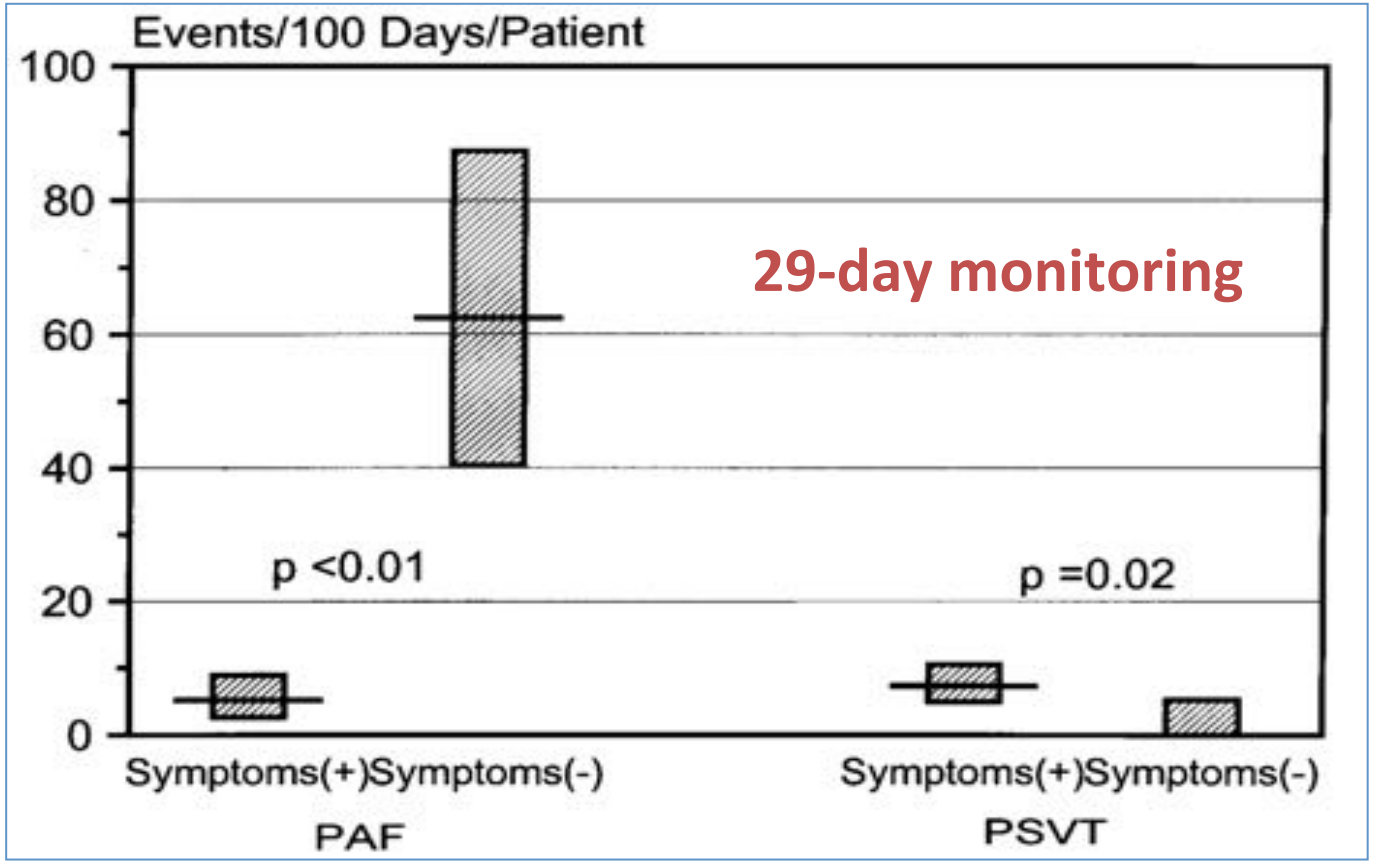
Unknown cause

Adams HP Jr, Stoke. Jan 1993; 24; 35-41

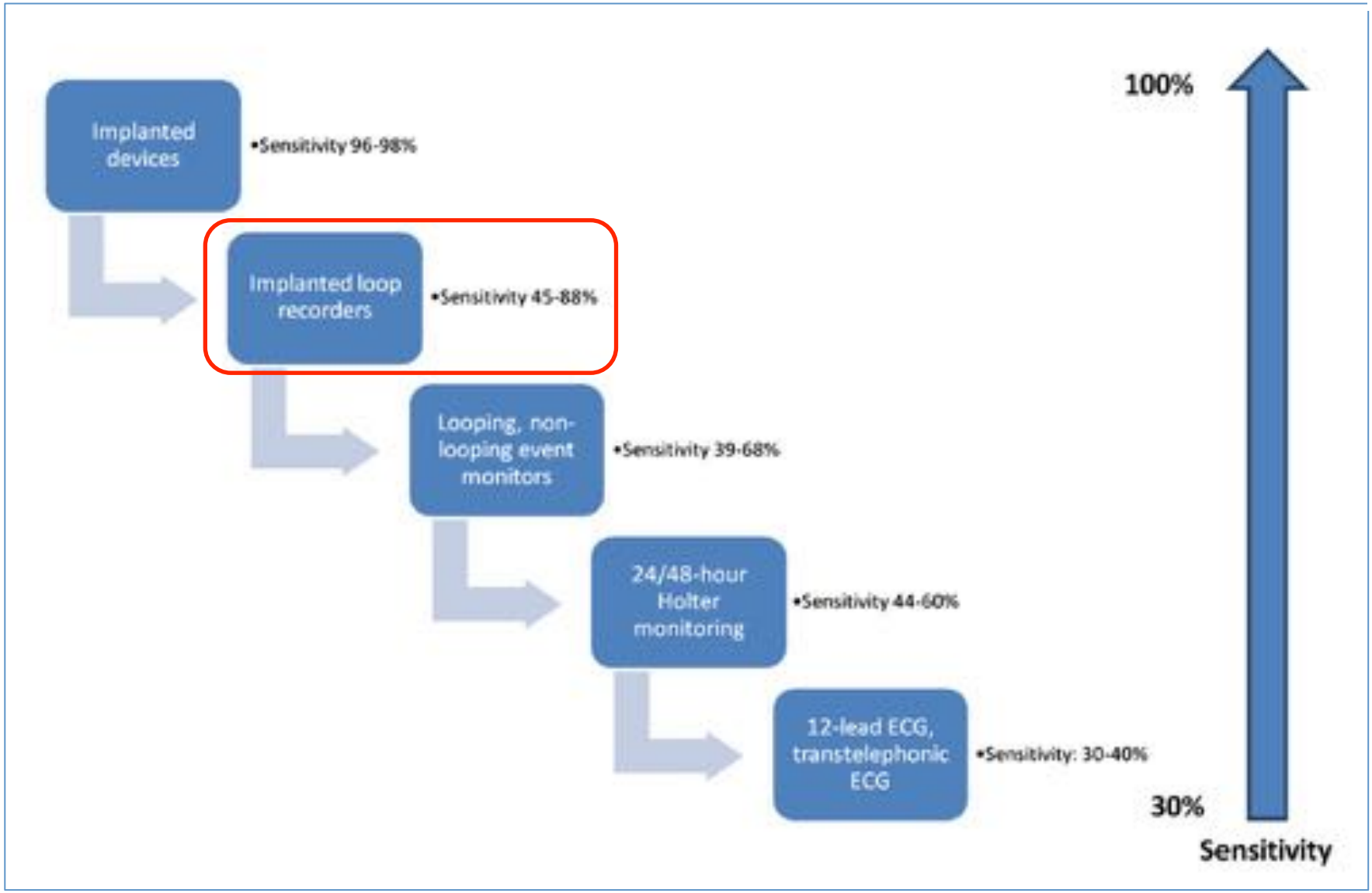
The CARAF Study: 142/674 pts (21%) = Asymptomatic

- Older
- Men
- No HTN
- Lower Heart Rate

Kerr C et al, Eur Heart J 1996



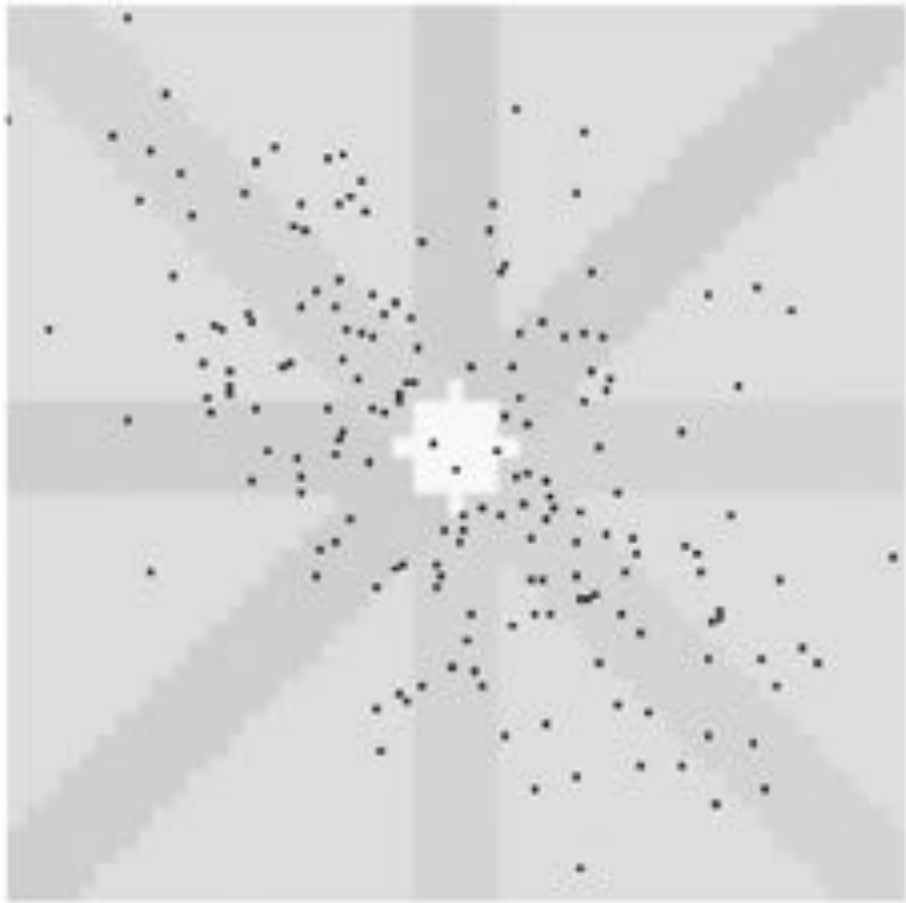
Pagé RL et al, Circulation 1994



SZ Rosero et al. Prog Cardiovasc Dis 2014

Dedicated devices:
Continuous monitoring and AF detection

Normal Sinus Rhytm



Atrial Fibrillation

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cryptogenic Stroke and Underlying Atrial Fibrillation

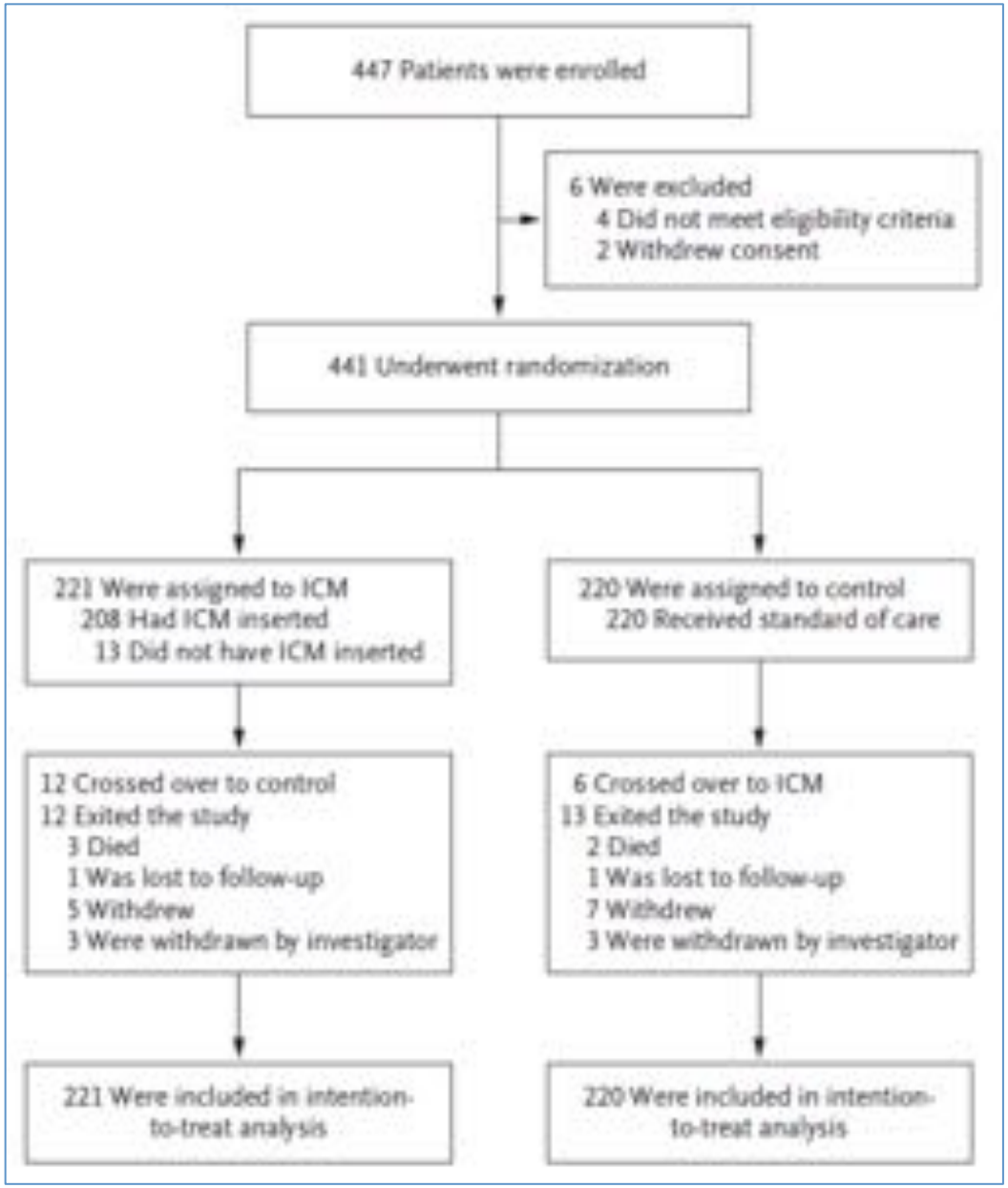
Tommaso Sanna, M.D., Hans-Christoph Diener, M.D., Ph.D., Rod S. Passman, M.D., M.S.C.E., Vincenzo Di Lazzaro, M.D., Richard A. Bernstein, M.D., Ph.D., Carlos A. Morillo, M.D., Marilyn Mollman Rymer, M.D., Vincent Thijs, M.D., Ph.D., Tyson Rogers, M.S., Frank Beckers, Ph.D., Kate Lindborg, Ph.D., and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

2014

≥ 40 y

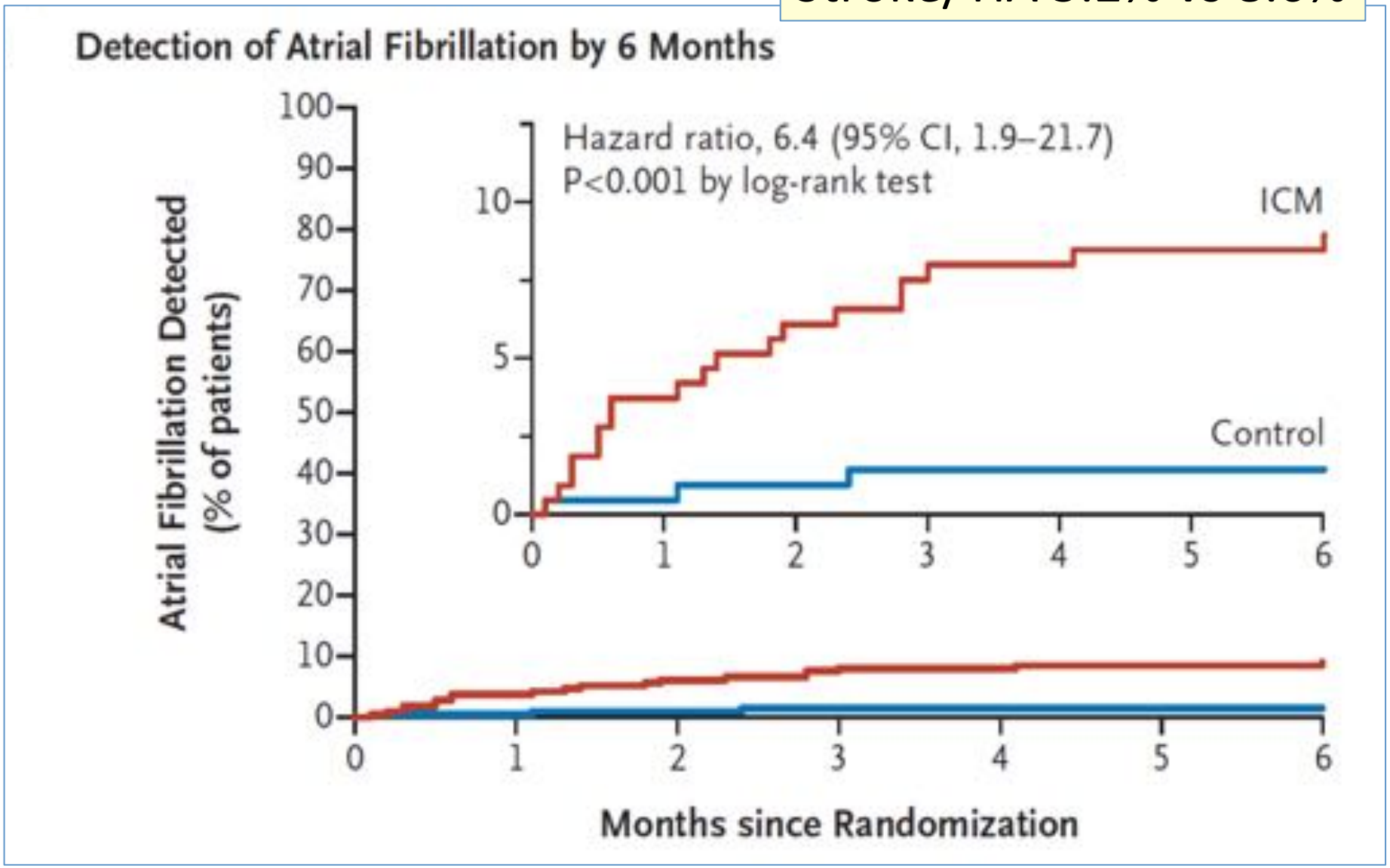
Cryptogenic stroke

No AF detected



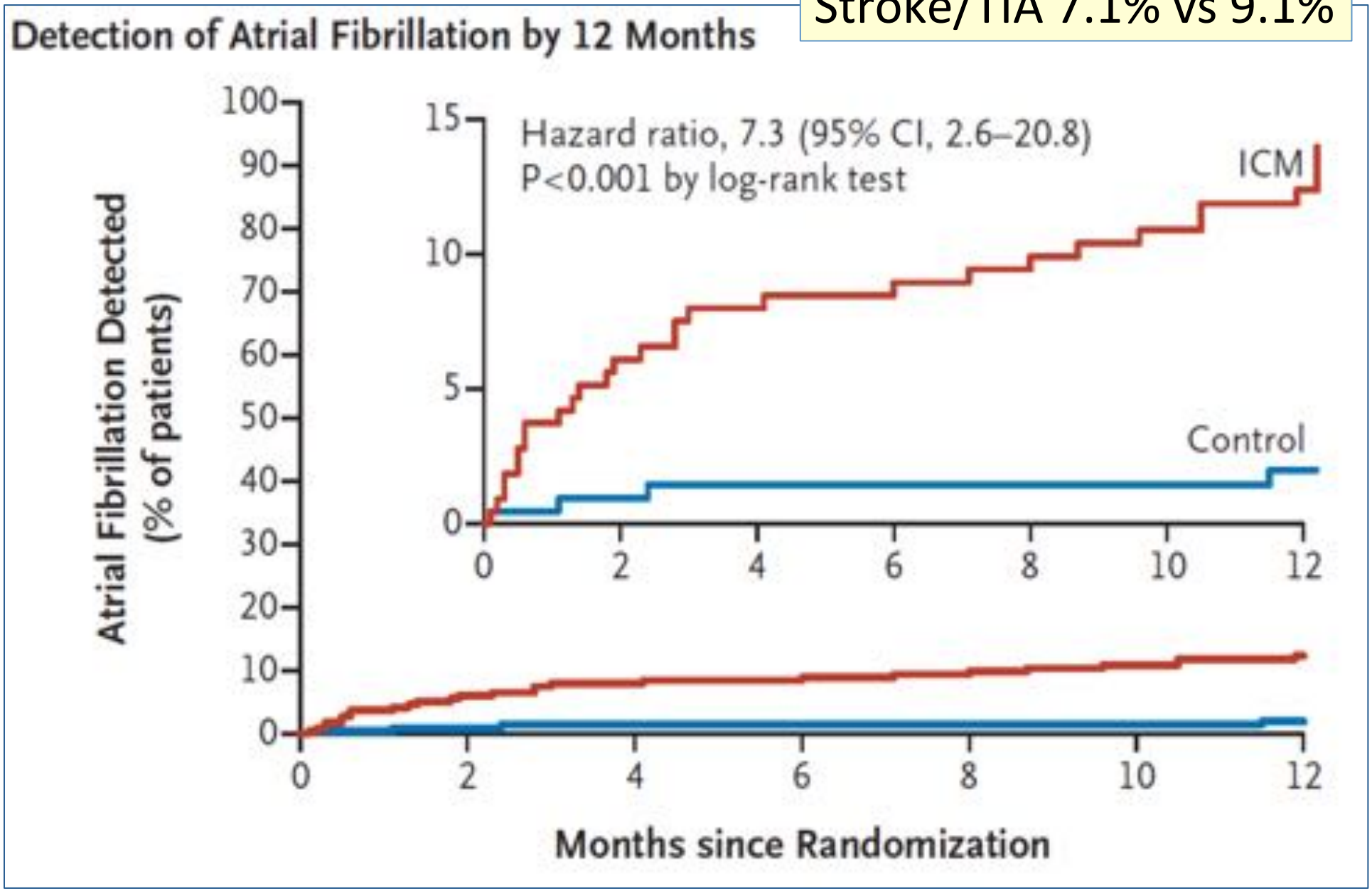
Sanna, NEJM 2014

Stroke/TIA 5.2% vs 8.6%



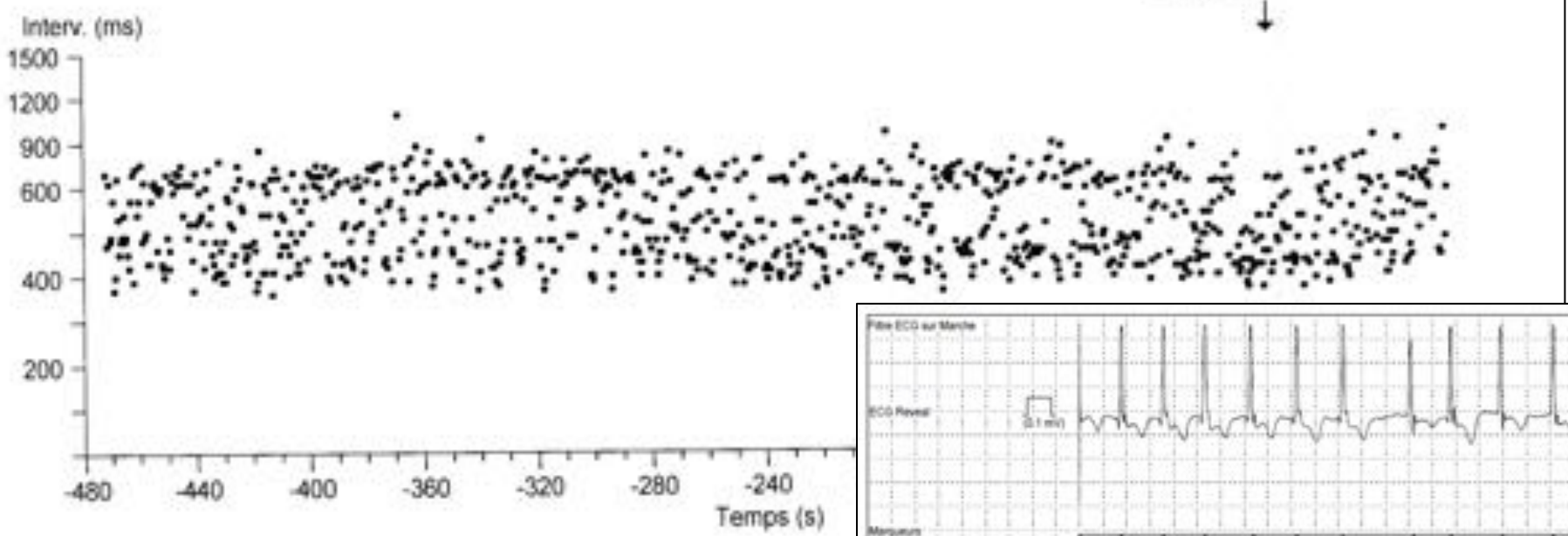
Sanna, NEJM 2014

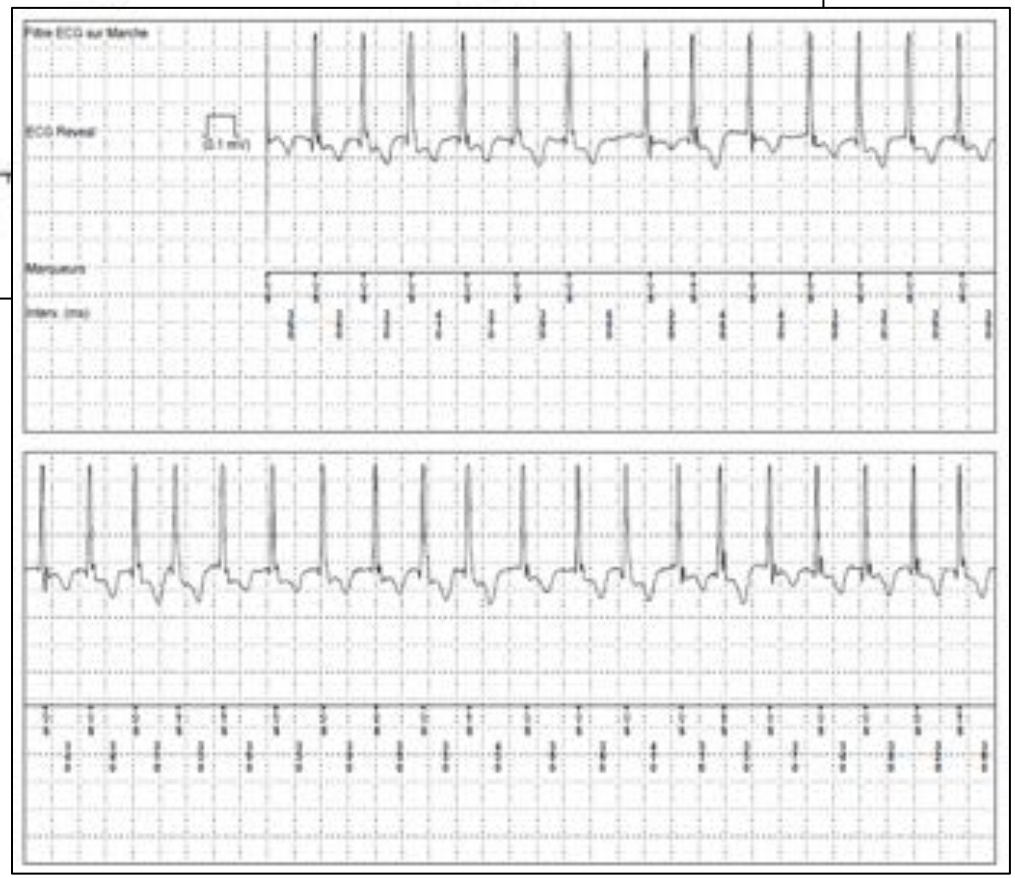
Stroke/TIA 7.1% vs 9.1%



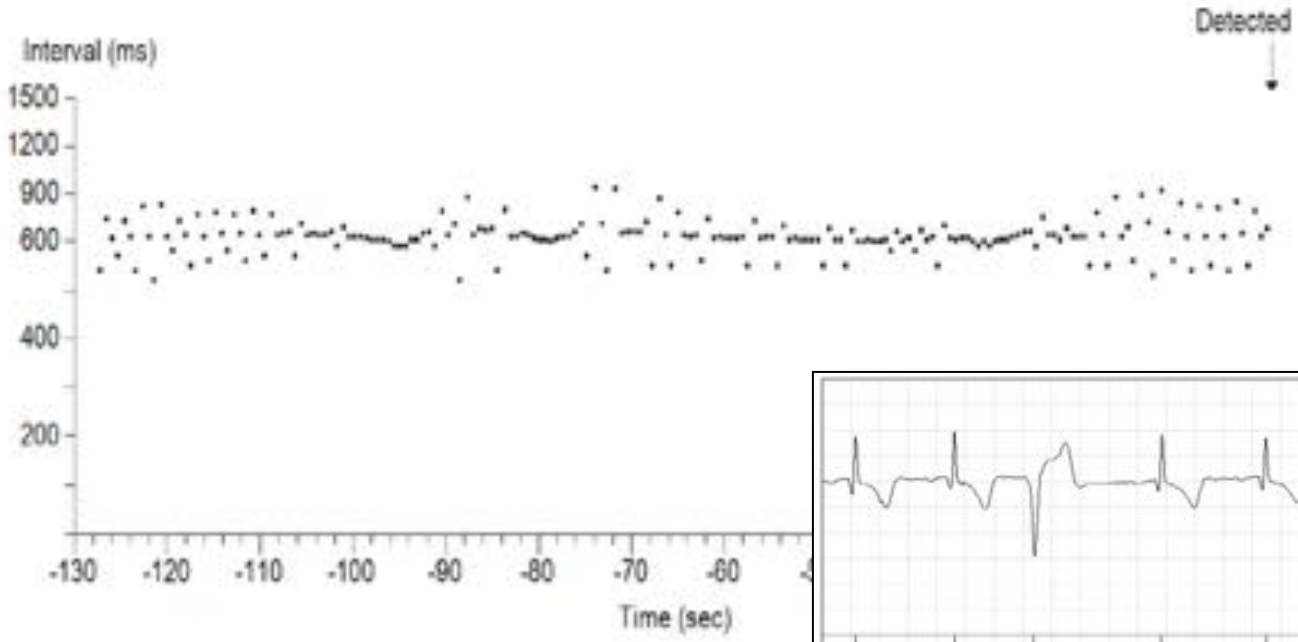
Sanna, NEJM 2014

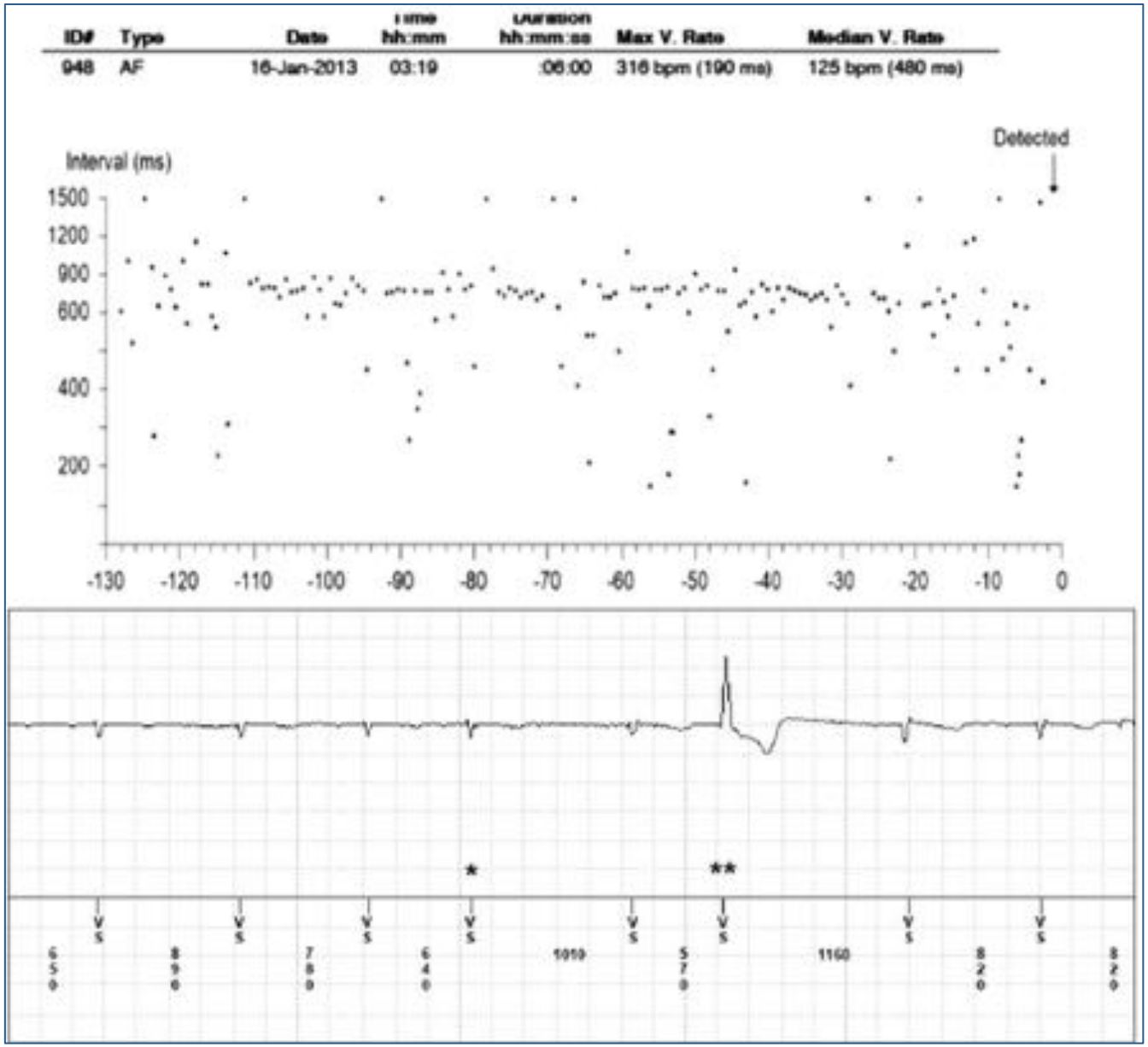
N°	Type	Date	Heure hh:mm	Durée hh:mm:ss	Fréquence V. max	Fréquence V. médiane
56	SYMPTOME	07-Oct-2014	13:12			





ID#	Type	Date	Time hh:mm	Duration hh:mm:ss	Max V. Rate	Median V. Rate
3620	AT	29-Nov-2013	13:02	02:00	100 bpm (600 ms)	92 bpm (650 ms)





N=40 pts

CT isthmus ablation

No history of AF

1 year FU

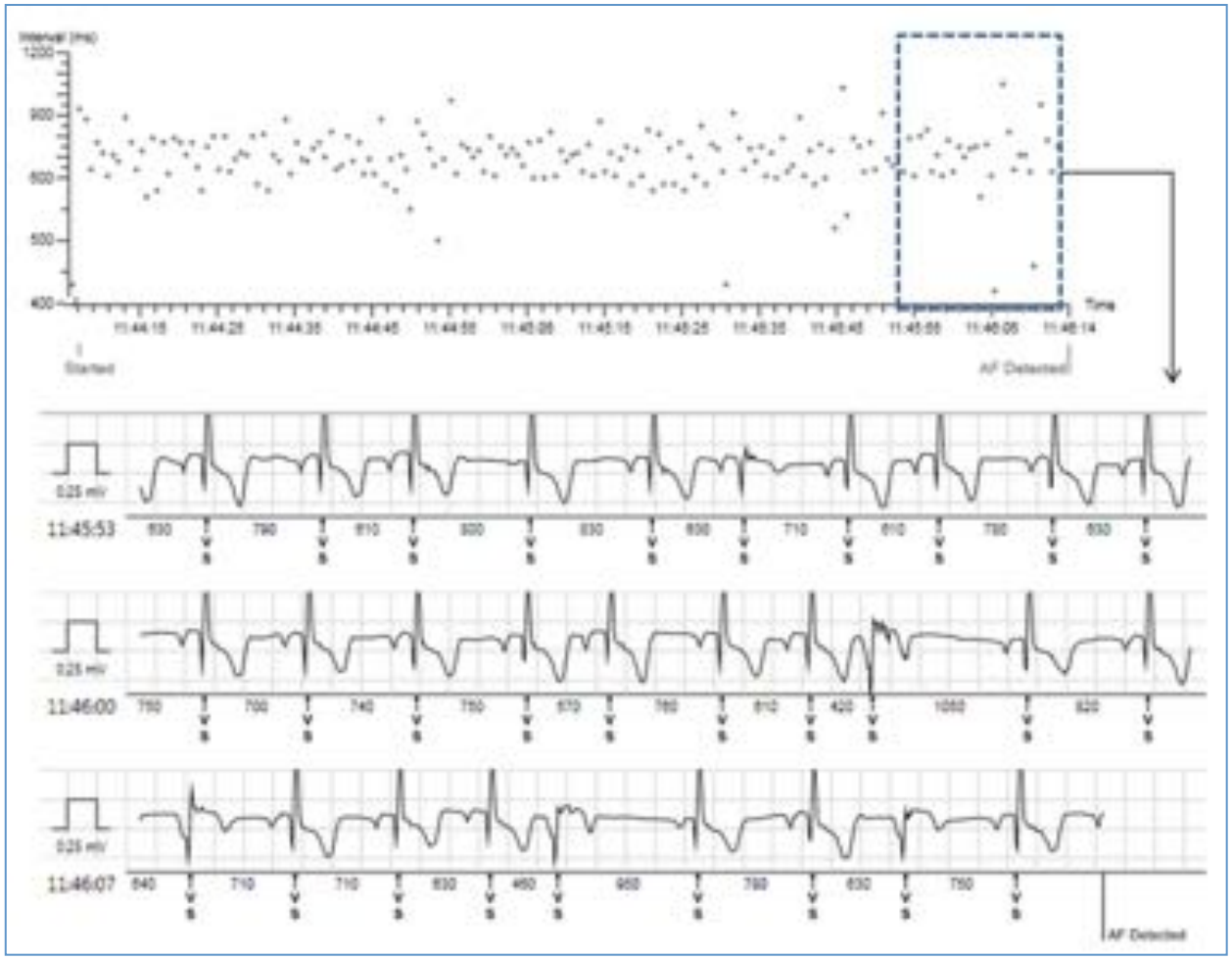
AF 55%, after 66 d

False positive 20%

Mittal et al., Heart Rhythm 2013

P-wave evidence as a method for improving algorithm to detect atrial fibrillation in insertable cardiac monitors

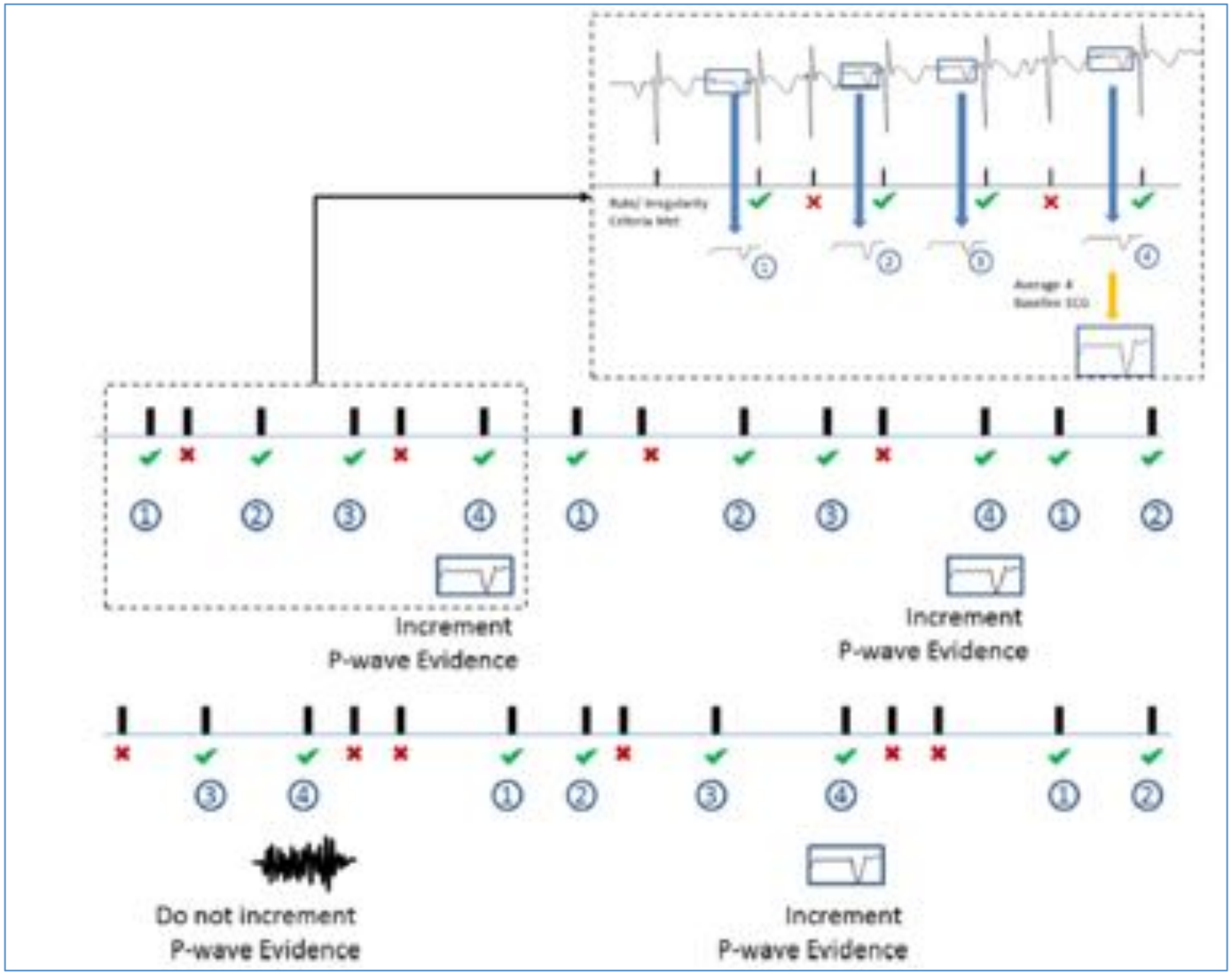
Helmut Pürerfellner, MD, FHRS,[*] Evgeny Pokushalov, MD,[†] Shantanu Sarkar, PhD,[‡] Jodi Koehler, MS,[‡] Ren Zhou, MS,[‡] Lubos Urban, MD,[§] Gerhard Hindricks, MD, FHRS[‖]



Heart Rhythm 2015

P-wave evidence as a method for improving algorithm to detect atrial fibrillation in insertable cardiac monitors

Helmut Pürerfellner, MD, FHRS,* Evgeny Pokushalov, MD,† Shantanu Sarkar, PhD,‡
Jodi Koehler, MS,‡ Ren Zhou, MS,‡ Lubos Urban, MD,§ Gerhard Hindricks, MD, FHRS‖



Heart Rhythm 2015

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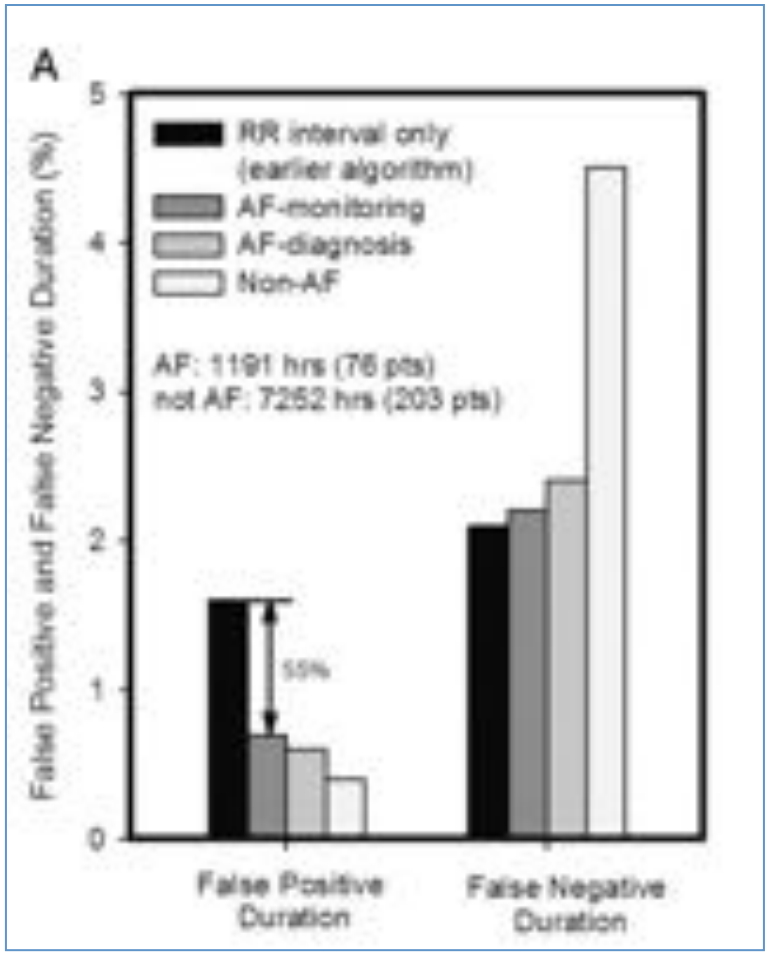
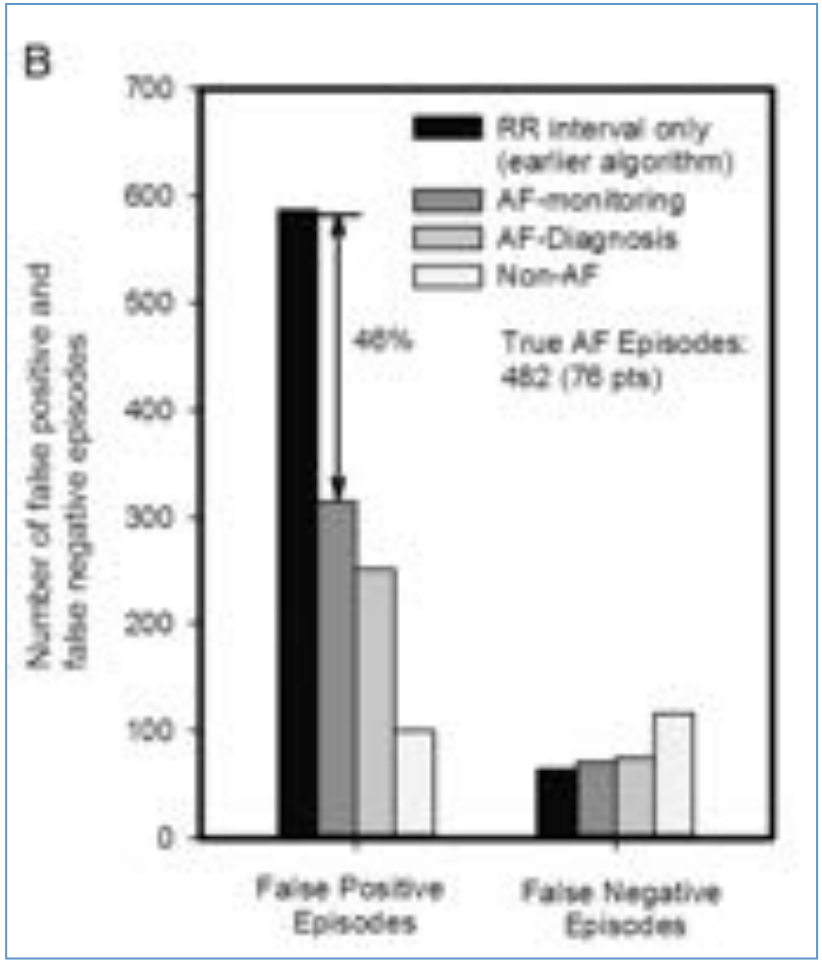
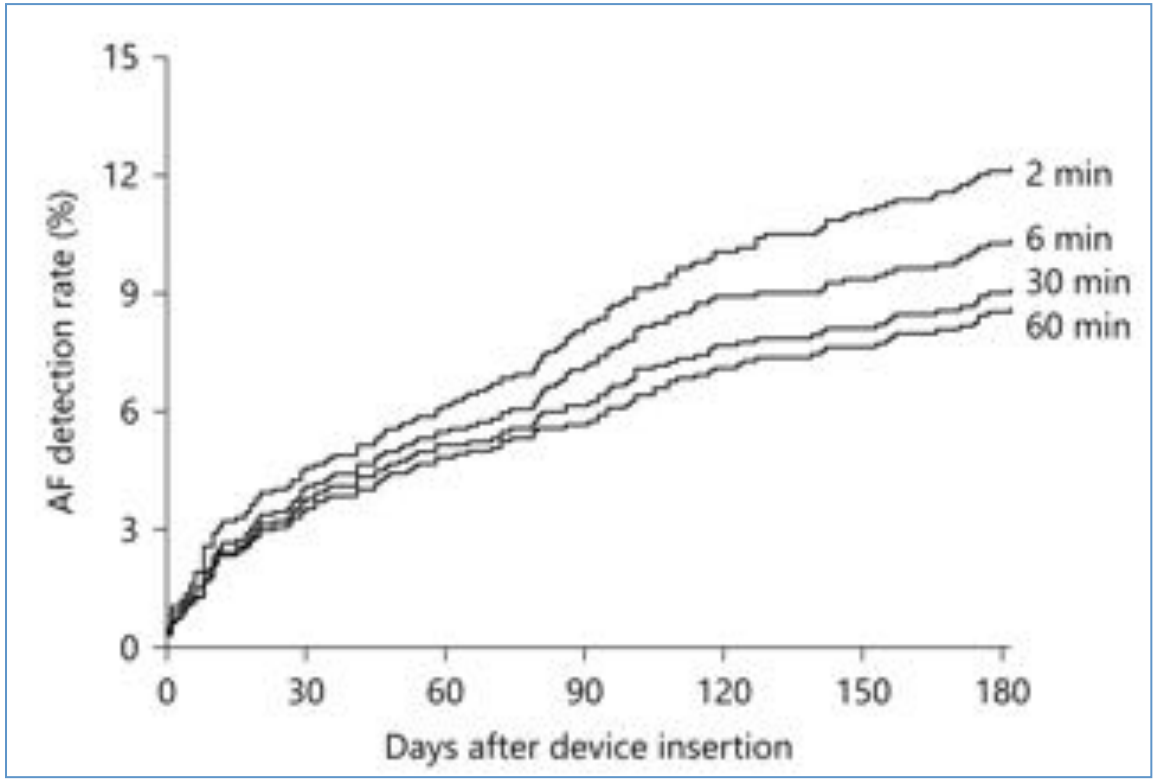




Heart Rhythm 2015

Real-World Experience with Insertable Cardiac Monitors to Find Atrial Fibrillation in Cryptogenic Stroke

Paul D. Ziegler[a] John D. Rogers[b] Scott W. Ferreira[c] Allan J. Nichols[d]
Shantanu Sarkar[a] Jodi L. Koehler[a] Eduardo N. Warman[a] Mark Richards[e]



Real-World (Reveal LINQ)

N = 1,247 pts (crypto stroke)

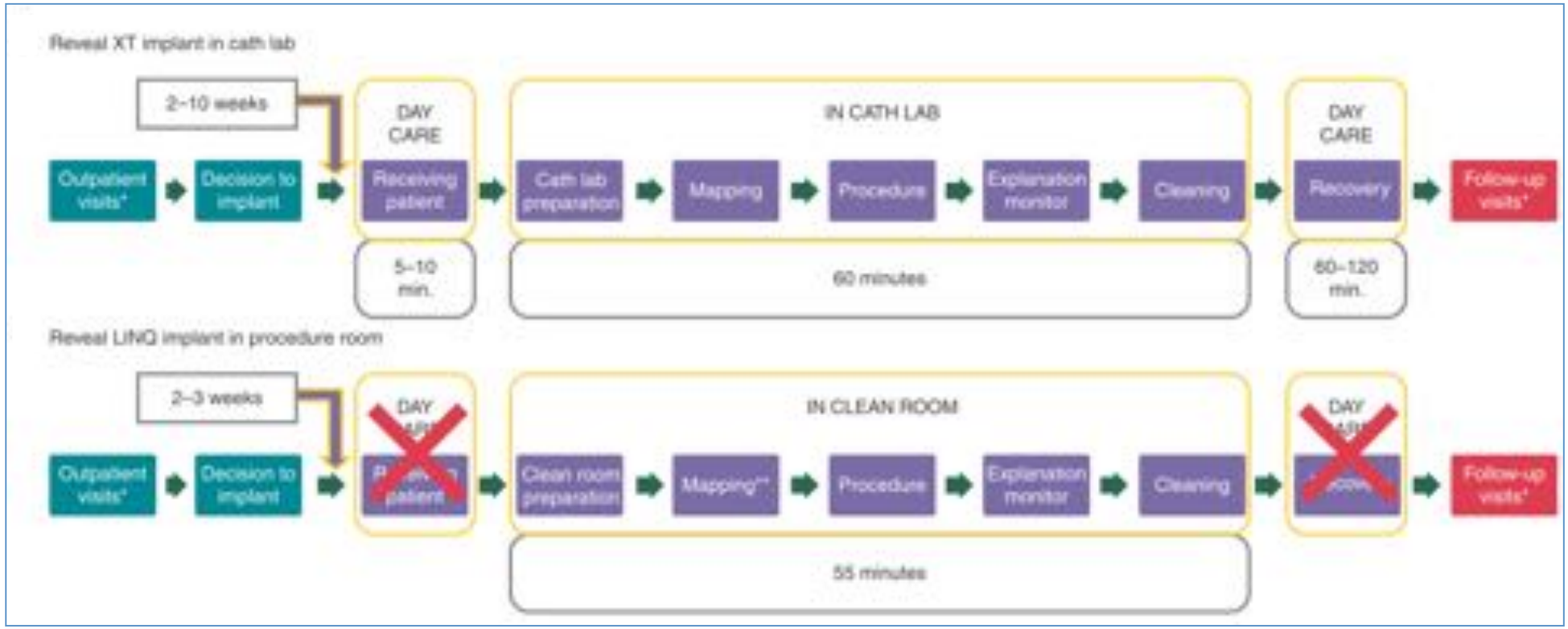
N = 147 pts with AF

Median: 58 days (11-101)

Cerebrovasc Dis 2015

Cost comparison of two implantable cardiac monitors in two different settings: Reveal XT in a catheterization laboratory vs. Reveal LINQ in a procedure room

Tim A. Kanters[1*], Claudia Wolff[2], David Boyson[3], Claude Kouakam[4], Trang Dinh[5], Leona Hakkaart[1], and Maureen P.M.H. Rutten-Van Mölken[1]



Europace 2015

Cost comparison of two implantable cardiac monitors in two different settings: Reveal XT in a catheterization laboratory vs. Reveal LINQ in a procedure room

Tim A. Kanters[1*], Claudia Wolff[2], David Boyson[3], Claude Kouakam[4], Trang Dinh[5], Leona Hakkaart[1], and Maureen P.M.H. Rutten-Van Mölken[1]

	Reveal XT in cath lab	Reveal LINQ in procedure room	Difference
Procedure-related costs			
Labour	€104	€42	−€63
Medication	€6	€2	−€4
Materials	€23	€20	−€3
Room-related costs			
Labour	€8	€7	−€1
Instruments/ equipment	€100	€5	−€95
Cleaning	€57	€4	−€53
Overhead costs			
Overhead costs	€197	€30	−€167
Hospital admission costs			
Hospital admission	€276	€0	−€276
Total costs difference			−€662

Europace 2015

Aix*Marseille université

Assistance Publique Hôpitaux de Marseille

Miniaturized Reveal LINQ insertable cardiac monitoring system: First-in-human experience

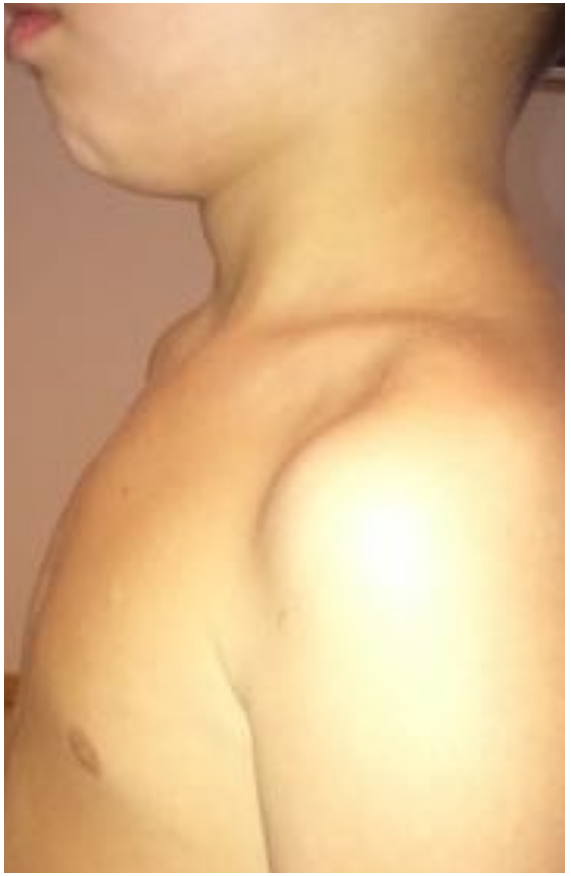
Helmut Pürerfellner, MD, FHRS,* Prashanthan Sanders, MBBS, PhD, FHRS,† Evgeny Pokushalov, MD,‡ Marco Di Bacco, PharmD,§ Tracy Bergemann, PhD,‖ Lukas R.C. Dekker, MD, PhD,¶ for the Reveal LINQ Usability Study Investigators

N = 30 pts

Adverse events (n = 10) through 1 month of follow-up

Key term	Procedure related	System related	Serious (Y/N)	Days after baseline visit
Cardiac arrest	Not related	Not related	N	0
Wound infection	Related	Not related	N	4
Palpitations	Not related	Not related	Y	3
Wound infection	Related	Not related	N	15
Atrial fibrillation	Not related	Not related	Y	7
Palpitations	Not related	Not related	N	22
Implantation site pain	Related	Related	N	33
Atrial fibrillation	Not related	Not related	Y	24
Angina pectoris	Not related	Not related	N	28
Implantation site pain	Related	Related	N	0

Heart Rhythm 2015



Conclusions

- ILR is not a perfect solution but, still, it is the best one available for continuous monitoring
- It has become truly micro-invasive nowadays
- Issues remain about : accuracy of the diagnosis, workload burden for reviewing records, and…