ČASR
ČESKÁ ASOCIACE PRO SRDEČNÍ RYTMUS

ČESKÁ KARDIOLOGICKÁ SPOLEČNOST

SASA

Typy a racionálne indikácie implantabilných záznamníkov

Ľuboš Urban
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	Biotronik BioMonitor^	Biotronik BioMonitor2	Medtronic Reveal LINQ	St. Jude Confirm^
Size				
Length (mm)	53.3	88.4	44.8	56.3
Width (mm)	42.7	15.2	7.2	18.5
Thickness (mm)	7.1	6.2	4.0	8.0
Volume (cc)	26	10.1	1.2	6.5
Weight (g)	12.5	5.0	2.5	12.0
Electrode spacing (mm)	26-43	75	37.7	39
Longevity (years)	4	4	3	3
Electrode storage	36 minutes	66 minutes	59 minutes	48 minutes
Atrial fibrillation (AF) features				
Minimum duration for detection	1 minute (nominal = 6 minutes)	1 minute (nominal = 6 minutes)	2 minutes	30 seconds
Episode data stored in data log			Up to 30 episodes^^	
Number of stored electrograms	Up to 55	Up to 55	Up to 14	Up to 147

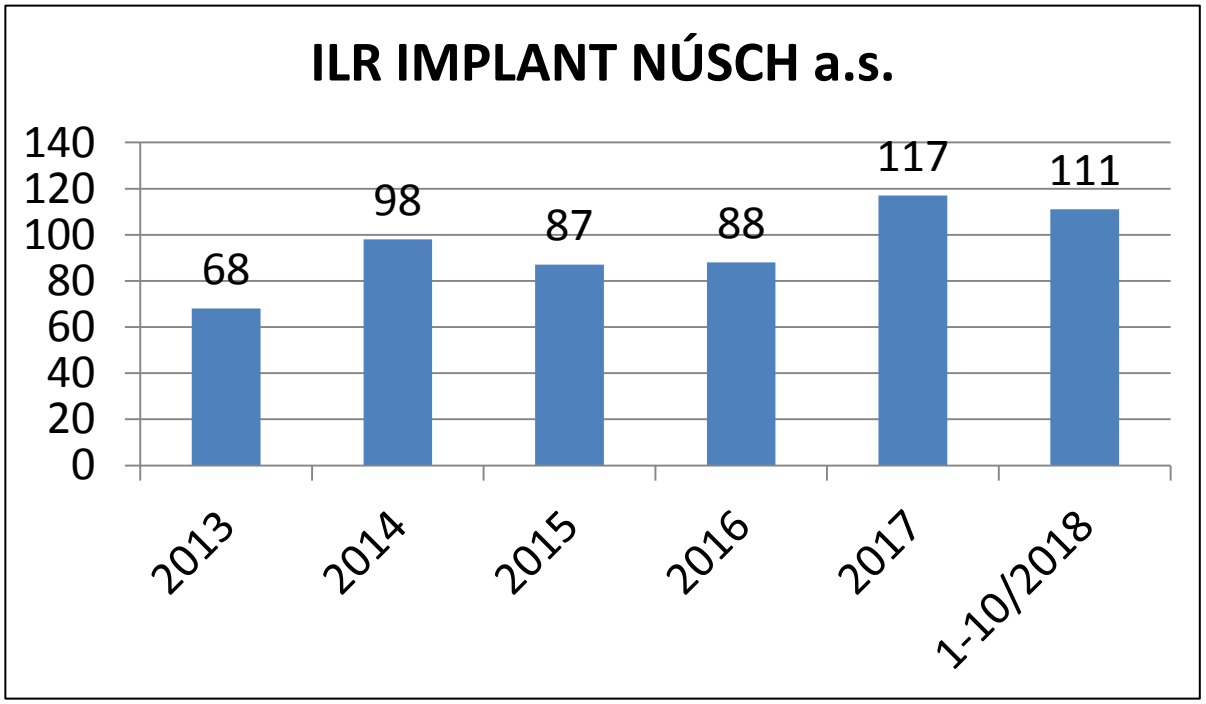
Medicínsko-ekonomický rozbor zdravotníckej pomôcky

(na účely kategorizácie zdravotníckych pomôcok a kategorizácie špeciálnych zdravotníckych materiálov)

- ***Opis cieľovej skupiny pacientov, prípadných podskupín pacientov a ich charakteristika:*** Implantovateľný EKG slučkový rekordér REVEAL LINQ je určený pacientom, ktorí si vyžadujú diagnostické, automatické a pacientom spustené subkutánne monitorovanie EKG pri s vybraných symptómoch (ako synkopa, dýchavičnosť, závraty...) a u pacientov s fibriláciou predsiení alebo nevysvetliteľnými arytmiami.

Predpokladaný počet pacientov, ktorí si budú vyžadovať monitoring EKG pomocou ŠZM Implantabilný EKG slučkový rekordér St. Jude Medical alebo inej zdravotnej pomôcky rovnakého typu v nasledujúcich piatich rokoch predstavuje:

v r. 2012 - 200 prípadov,
v r. 2013 - 300 prípadov,
v r. 2014 - 400 prípadov,
v r. 2015 - 500 prípadov,
v r. 2016 - 600 prípadov,
v r. 2017 - 700 prípadov.



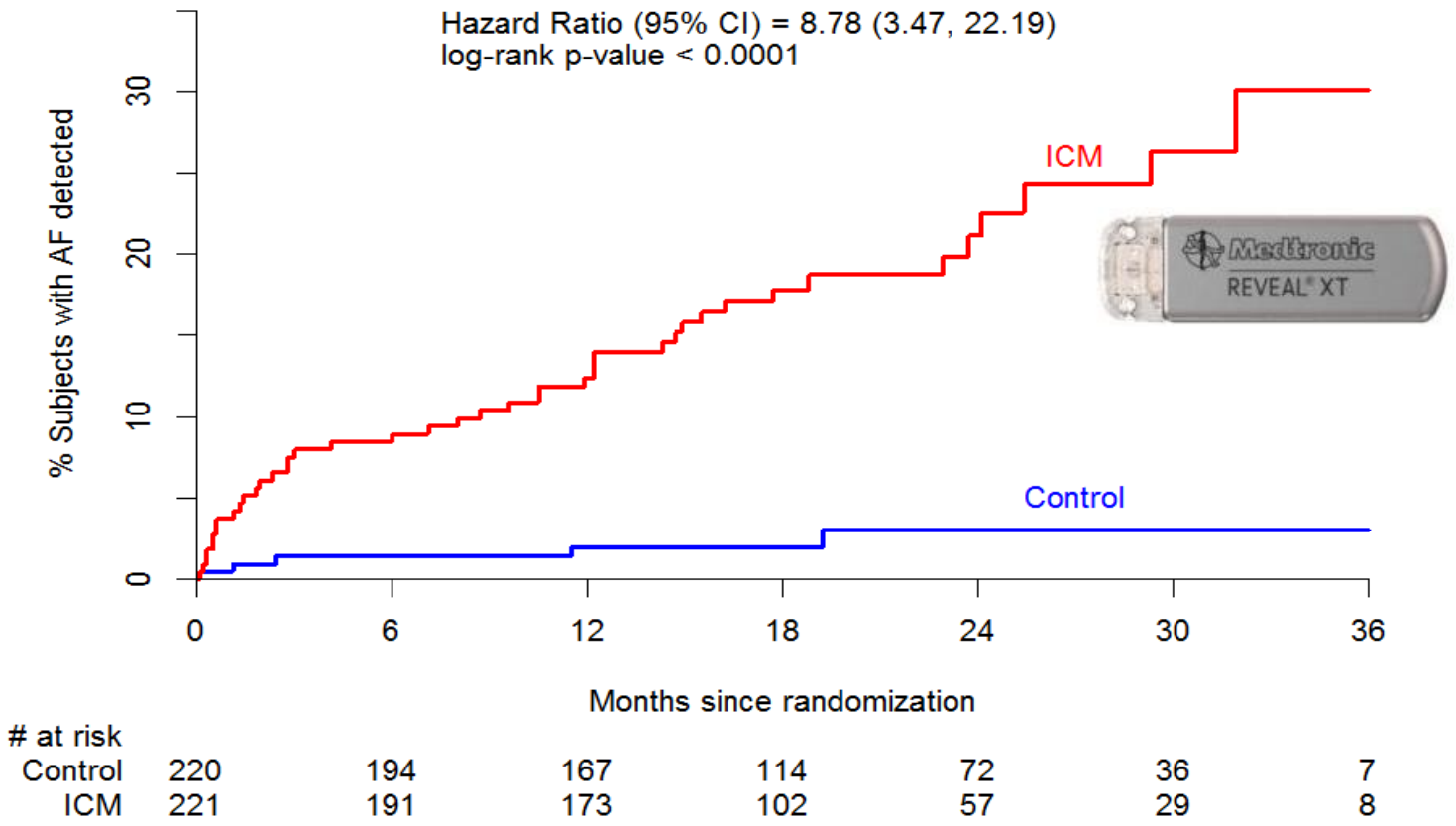
Europace (2016) **18**, 1609–1678
doi:10.1093/europace/euw295

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

Recommendations for screening for atrial fibrillation

In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.	IIa	B	18, 128
Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk.	IIb	B	130, 135, 157

CRYptogenic STroke and underlying AtriaL Fibrillation (CRYSTAL AF)



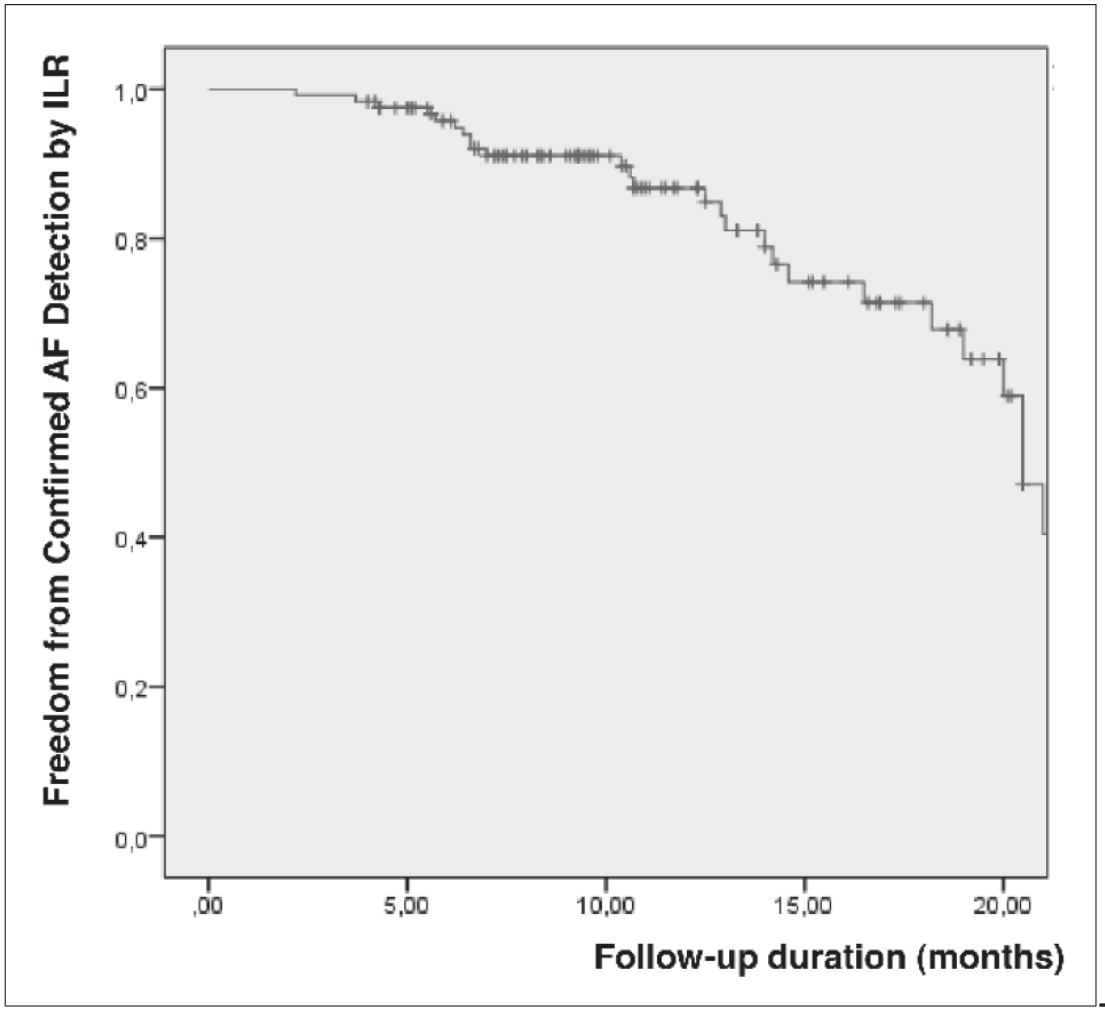
Rate of detection in ICM arm was 30% vs 3% in control arm

36 month FU

	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 ≥ 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

Detection of atrial fibrillation in patients with embolic stroke of undetermined source by prolonged monitoring with implantable loop recorders

Carsten Israel[1]; Alkisti Kitsiou[2]; Malik Kalyani[1]; Sameera Deelawar[1]; Lucy Ekosso Ejangue[1]; Andreas Rogalewski[2]; Christoph Hagemeister[2]; Jens Minnerup[3]; Wolf-Rüdiger Schäbitz[2]



N= 123

ILR - 20 days after ESUS

Mean FU: 12.7±5.5 m

Daily ILR analysis

First AF after 3.6±3.4 m

Thromb Haemost 2017; 117: 1962–1969.

AF detected by continuous ECG monitoring using ILR to prevent stroke in individuals at risk (the LOOP study)

Inclusion criteria	Exclusion criteria
• Age 70-90 y	• Known AF or ongoing OAC • Existing contraindication to OAC • History of severely uncorrected congenital heart disease, severe valve stenosis, cardiomyopathy, myocarditis, or pericarditis • Cardiac pacemaker, cardiac resynchronization therapy, or implantable cardioverter-defibrillator • Major organ transplant • Recent thoracic or cardiac surgery or on a waiting list for major surgery • Current malignancy or chemotherapy and/or radiation therapy (except for stable, localized prostate cancer, basal or squamous cell carcinoma of the skin, or cervical intraepithelial neoplasia with a life expectancy >2.5 y) • Permanent dialysis • Alcohol or drug abuse • Unwillingness to participate
• Previously diagnosed as having ≥1 baseline disease: o Hypertension (with/without medical treatment) o Diabetes mellitus (type 1 or 2, with/without medical treatment) o Heart failure (NYHA II-IV or ventricular ejection fraction <50%) o Previous stroke (diagnosed at hospital and preferably verified by imaging; a transient ischemic attack is not accepted as inclusion criterion)	

Denmark (ILR 1500 pts, control 4500 pts), FU 4 years
Enrollment 2014-2016, end of FU 2020, ITT analysis
<u>primary end point: time</u> to first stroke or SE

Am Heart J 2017;187:122-32.

Diagnosis of silent atrial fibrillation

Year	Trial	Device Indication	Clinical Profile of Patients	Incidence of AF
2002	Gillis et al[37]	PPMs for SND	All	157/231 (68%)
2003	MOST[38]	PPMs for SND	All	156/312 (50%)
2010	TRENDS[21]	PPMs and ICDs for all indications	History of prior stroke, no history of AF, no OAC use, ≥1 stroke risk factor	45/163 (28%)
2012	TRENDS[39]	PPMs and ICDs for all indications	History of prior stroke, no history of AF, no OAC use, ≥1 stroke risk factor	416/1368 (30%)
2012	A[40]			2580 (34.7%
2013	H			445 (55.3%)
2014	G			24 (17.4%)
2015	B et al[43]	indications		09 (25.7%)

Incidence of newly detected AF in pts with PPMs or ICDs

17.4% – 68%

Study	No. of Patients	AF Definition	Monitoring Duration	AF Detection Yield
Cotter et al[46]	51	2 minutes	Mean 229 (116) days	25.5%
Ritter et al				
Etgen et al				
Rojo-Marti et al[49]				
Jorfida et al[50]	54	5 minutes	6–28 months	46%
SURPRISE[51]	85	2 minutes	569 ± 310 days	16.1%
CRYSTAL AF[52,53]	221	>30 seconds	Minimum 6 months	8.9% at 6 months, 12.4% at 12 months, 30.0% at 36 months
Poli et al[54]	74, ≥1 AF risk factor	2 minutes	Minimum 6 months	28% at 6 months, 33.3% at 12 months

New AF detected by ICM in pts with cryptogenic stroke

16% - 46%

Clinical Cardiology. 2017;40:413–418.

%AF dní pri kontinuálnom EKG monit.

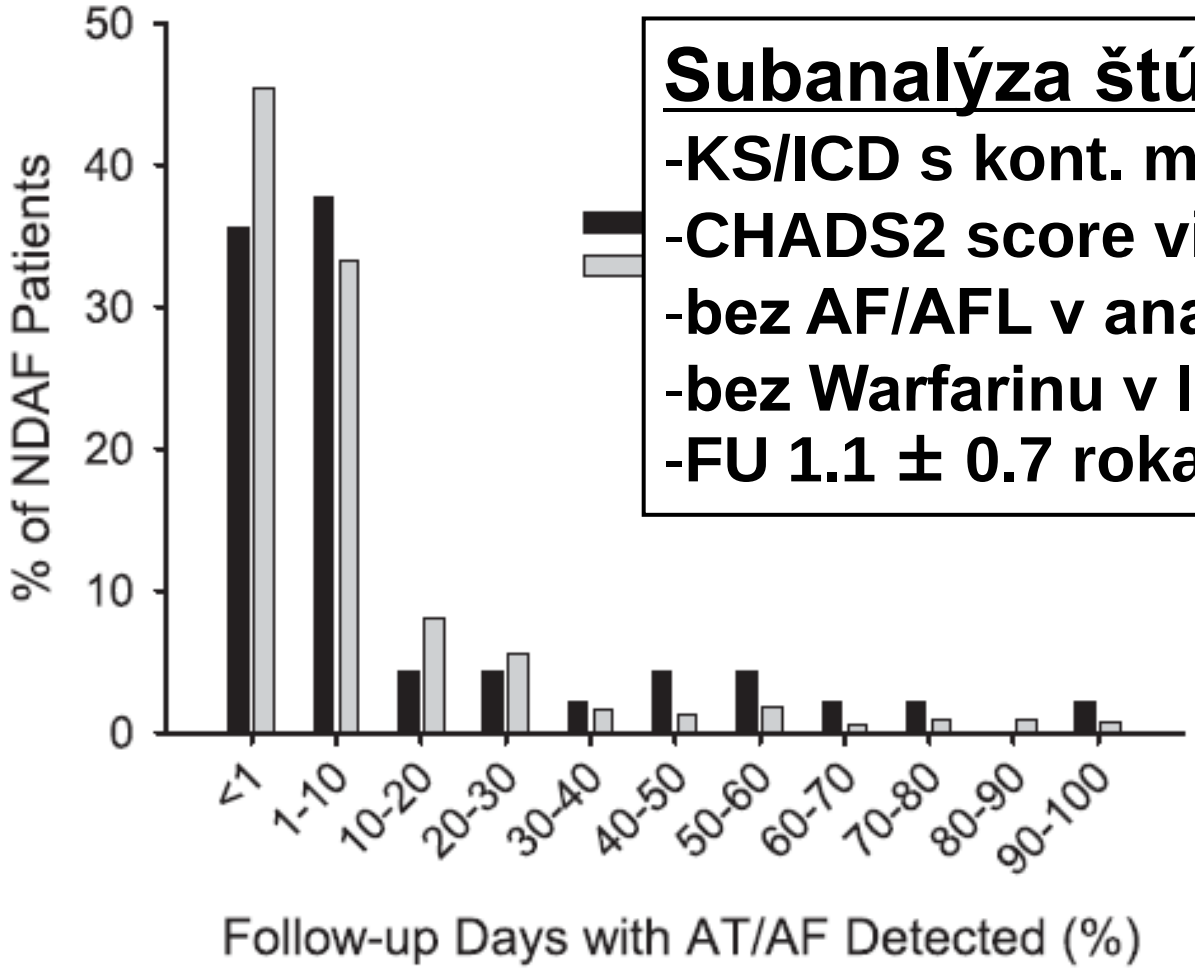


Figure 2. Distribution of the percentage of days with AT/AF detected among NDAF patients.

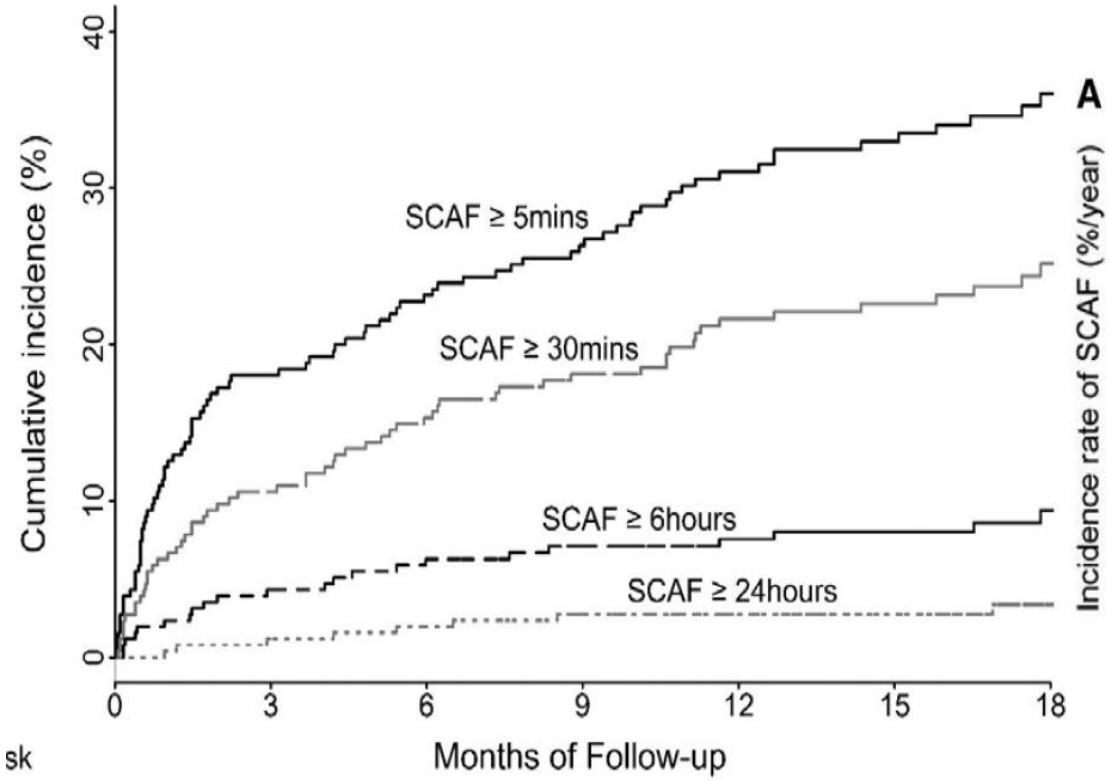
Subanalýza štúdie TRENDS

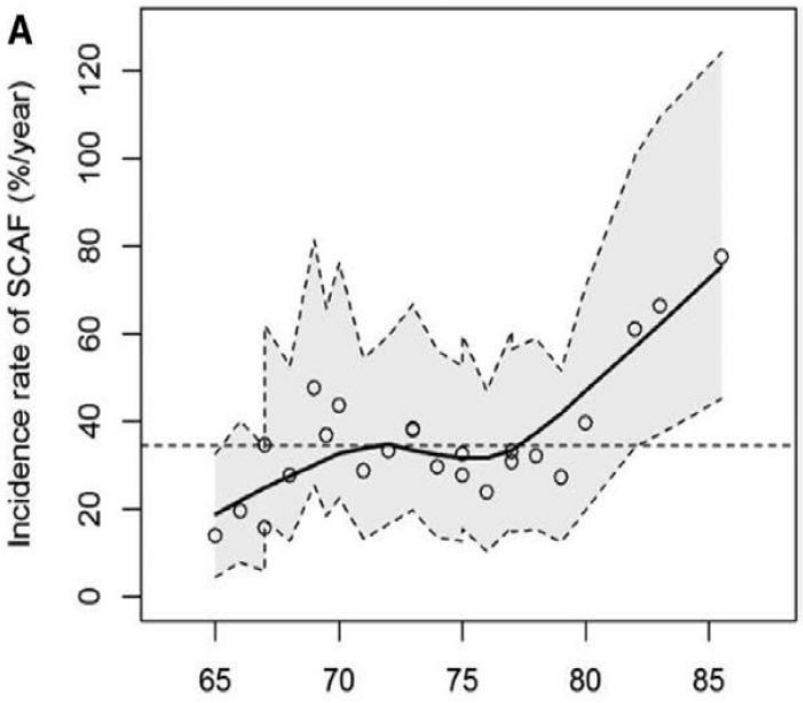
- **KS/ICD s kont. monitoringom EKG**
- **CHADS2 score viac ako 1**
- **bez AF/AFL v anamnéze**
- **bez Warfarinu v liečbe**
- **FU 1.1 ± 0.7 roka**

Stroke. 2010 Feb; 41(2):256-60

Subclinical Atrial Fibrillation in Older Patients

Pts ≥65 years; no history of AF
any of the following: CHA2DS2-VASc score of ≥2, sleep apnea, or BMI >30 kg/m2
LA ≥ 44mm or volume ≥ 58 ml or NT-proBNP ≥290 pg/ml
implanted with ICM St. Jude CONFIRM-AF



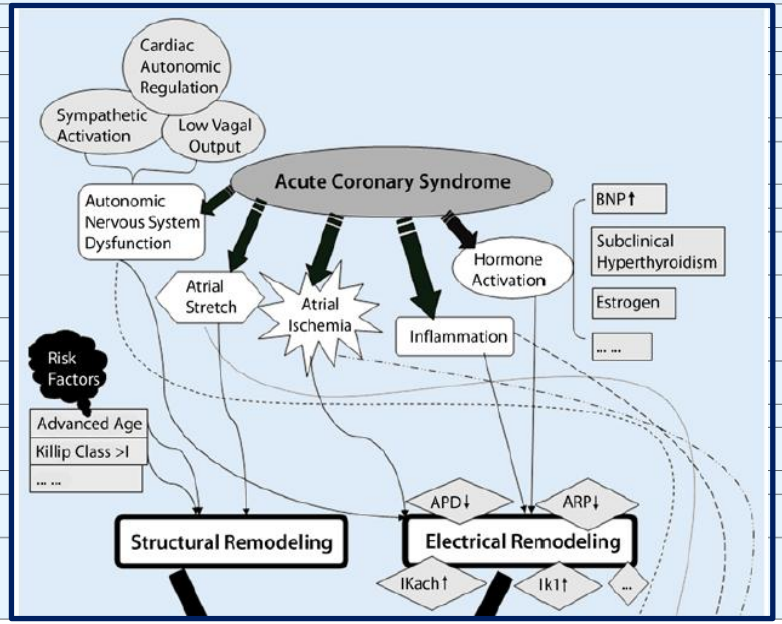


Circulation. 2017;136:1276–1283.

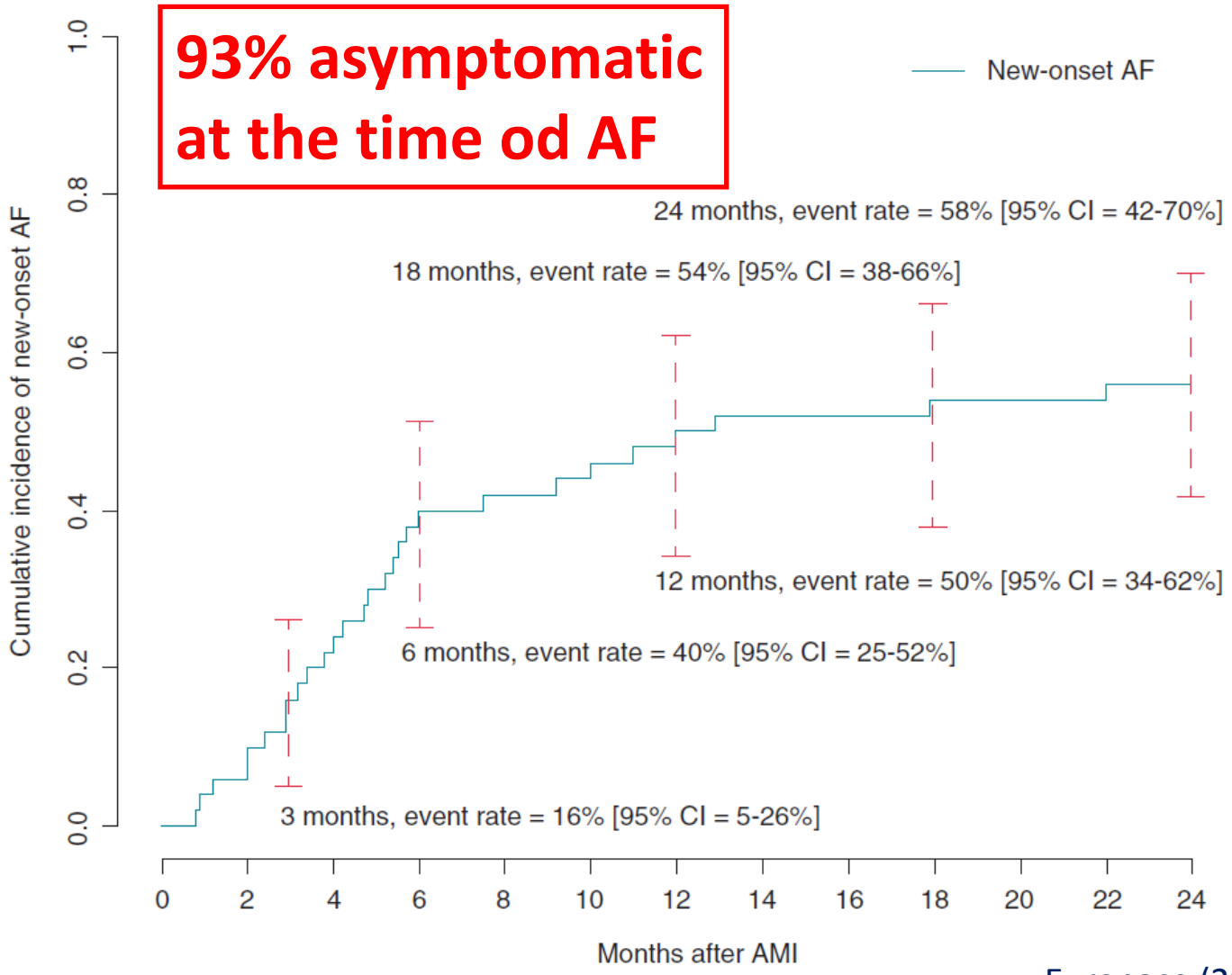
New-onset AF complicating acute coronary syndrome

Author	Publication year	Trial	Study type	Patients (*n*)	ACS type	Ischemic territory	Involved coronary vessel	Incidence of new-onset AF (%)	Prognosis of new-onset AF patients
Stamboul et al. [7]	2014	ns	Prospective	849	AMI	ns	ns	21	In-hospital mortality was 12.2%
Lopes et al. [9]	2013	EARLY ACS	Prospective	9,242	NSTEACS	ns	ns	6.0	30-day mortality was 7.6%
Poci et al. [30]	2012	PRACSIS	Prospective	2,335	ACS	ns	ns	10.2	30-day mortality was 15%
Mrdovic et al. [10]	2012	RISK-PCI	Prospective	2,096	STEMI	ns	ns	6.2	30-day mortality was 21%
Zusman et al.									
Wu et al. [12]									ortality was 16%
Yoshizaki et al.									
Lin et al. [13]	2011	ns	Retrospective	783	STEMI	ns	ns	10.9	30-day mortality was 15.3%
Aronson et al. [15]	2011	ns	Prospective	1,169	AMI	ns	ns	9.4	ns
Jabre et al. [31]	2011	ns	Prospective	3,220	AMI	ns	ns	19	ns
Hwang et al. [14]	2011	ns	Prospective	401	AMI	Left atrium	LCx	8.2	ns
Alasady et al. [43]	2011	ns	Retrospective	2,460	AMI	Atrium	Right and left coronary artery atrial branch	6	ns
Jons et al. [33]	2010	CARISMA						37	ns
Bahouth et al. [16]	2010	ns						8.4	ns
Lau et al. [17]	2009	ACACIA						4.4	ns
Saczynski et al. [18]	2009	ns						13.3	30-day mortality was 26.5%
Lopes et al. [20]	2008	ns						7.5	1-year mortality was 10%
Siu et al. [21]	2007	ns						13.7	ns
Aronson et al. [22]	2007	ns						11.3	ns
Ramani et al. [23]	2007	ns						10.8	ns
Kober et al. [24]	2006	VALIANT						12.4	3-year mortality was 36.7%
Mcmurray et al. [34]	2005	CAPRICORN						2.3	ns
Kinjo et al. [26]	2003	OACIS						12	1-year mortality was 18.9%
Goldberg et al. [27]	2002	ns						13	5-year mortality was 35%
Wong et al. [28]	2000	GUSTO-III						6	1-year mortality was 15%
Rathore et al. [41]	2000	CCP						22.1	1-year mortality was 48.3%
Pedersen et al. [6]	1999	TRACE						21	5-year mortality was 56%
Crenshaw et al. [32]	1997	GUSTO-I						10.4	1-year mortality was 21.5%
Hod et al. [44]	1987	ns						3	ns

The incidence of new-onset AF is 2.3–37%

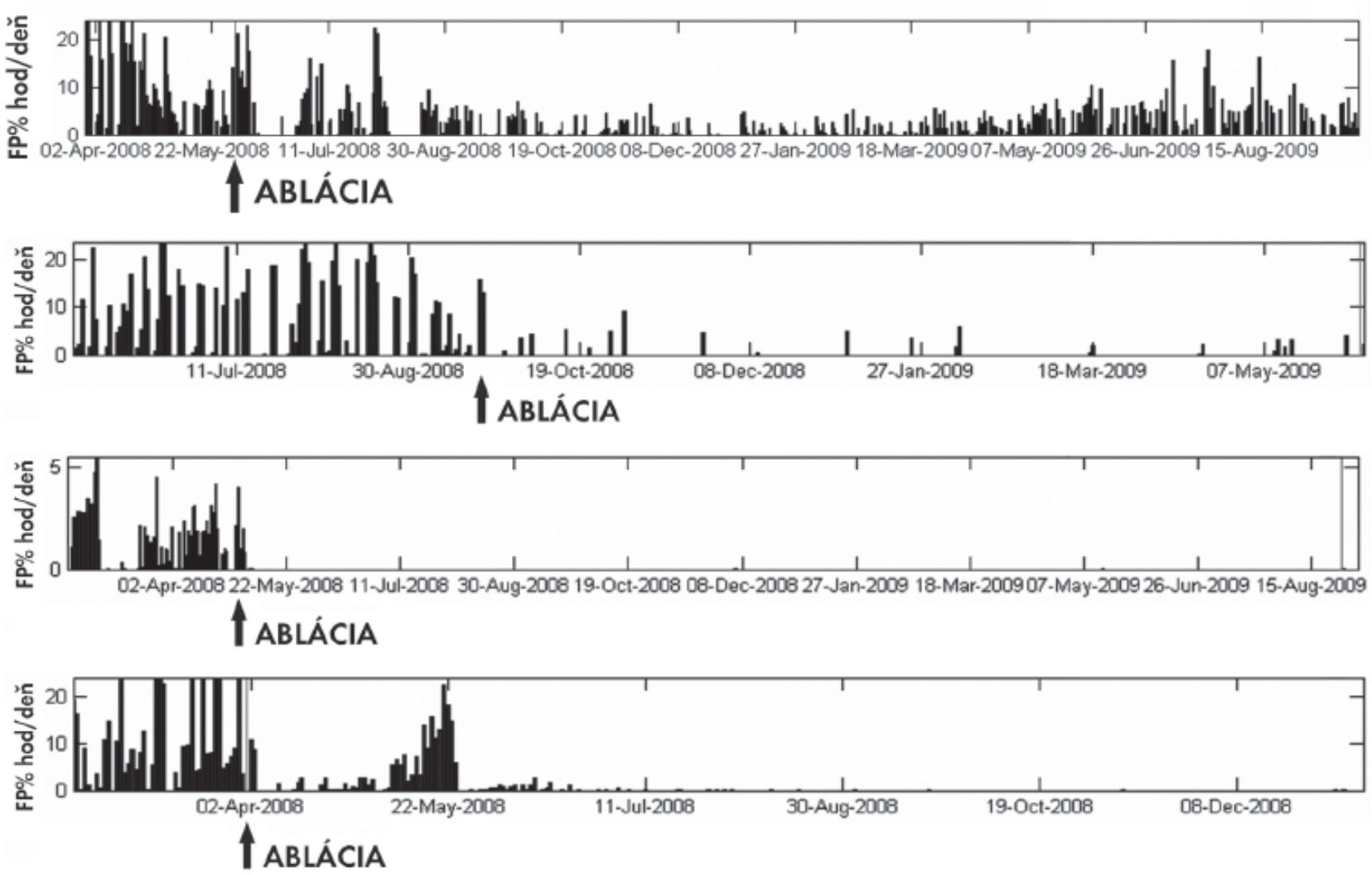


New onset-AF detected by continuous rhythm monitoring after acute myocardial infarction (LVEF >40%)



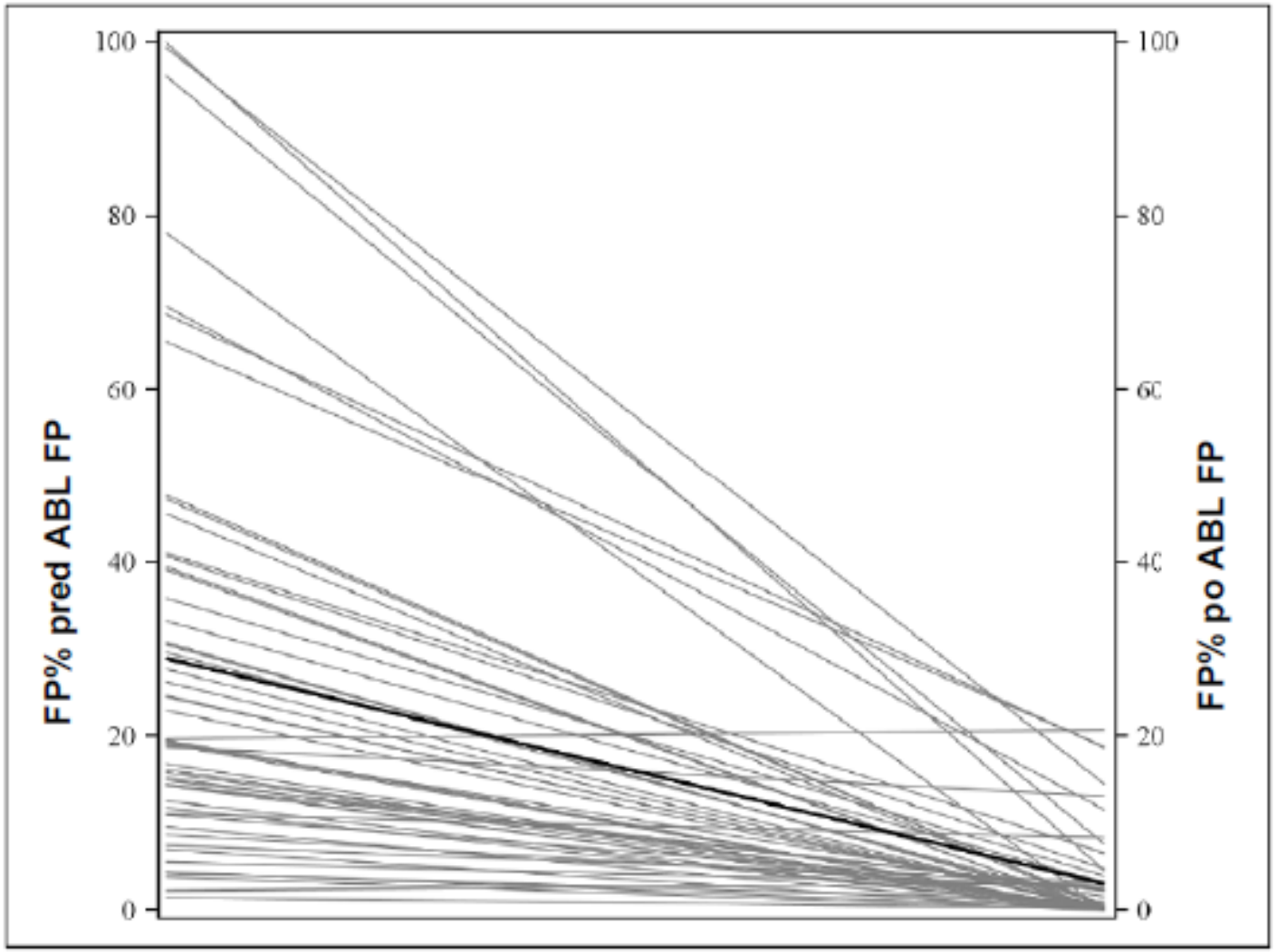
Europace (2017), 1–8.

Distribúcia FP u rôznych pacientov
dáta získané kontinuálnym monitoringom EKG

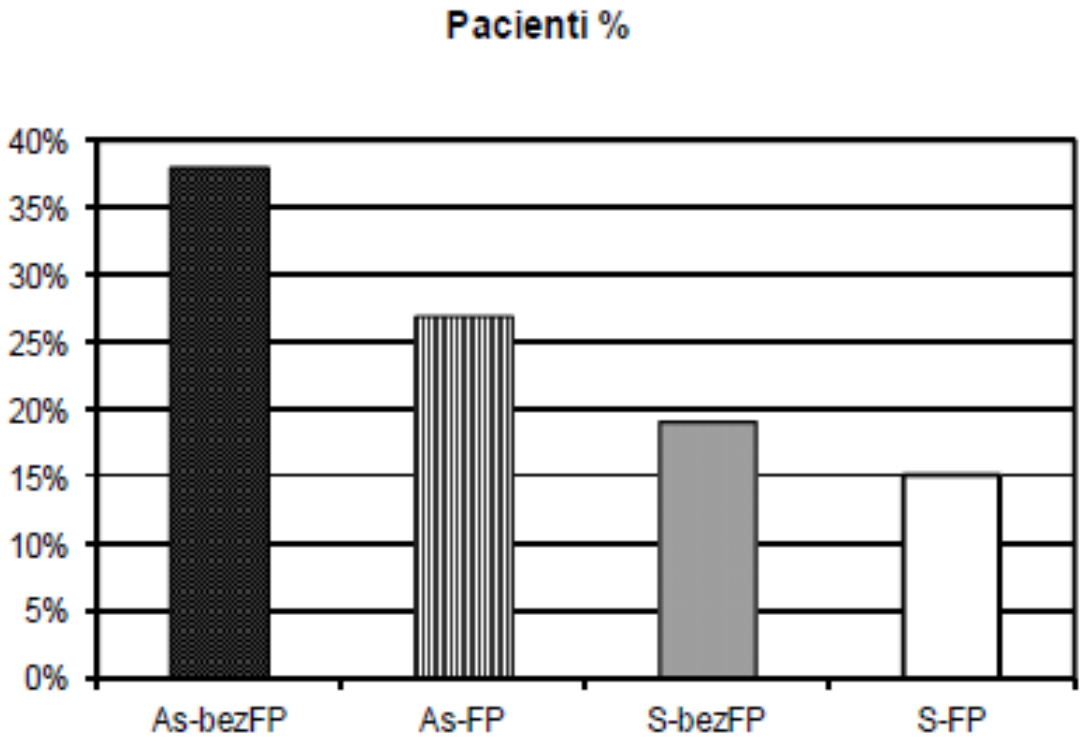


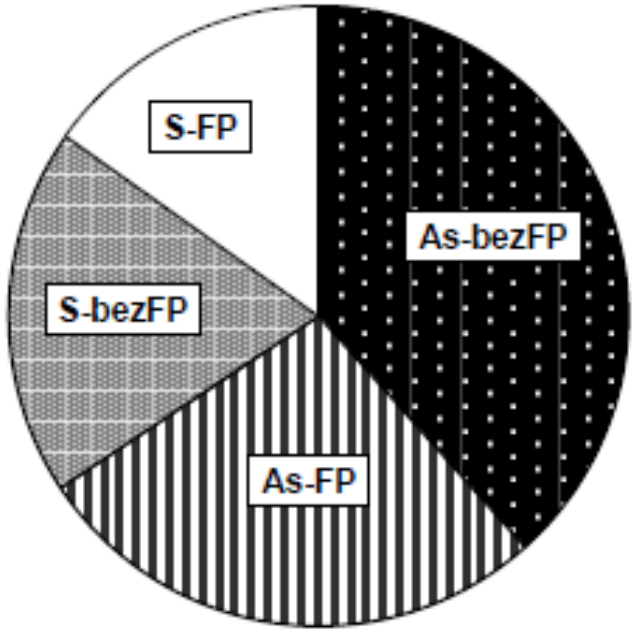
Čas strávený vo FP pred a po ABL FP

Dáta získané kontinuálnym monitoringom EKG



Analýza recidív FP a symptómov po ABL z dát ziskaných slučkovým monitorom EKG





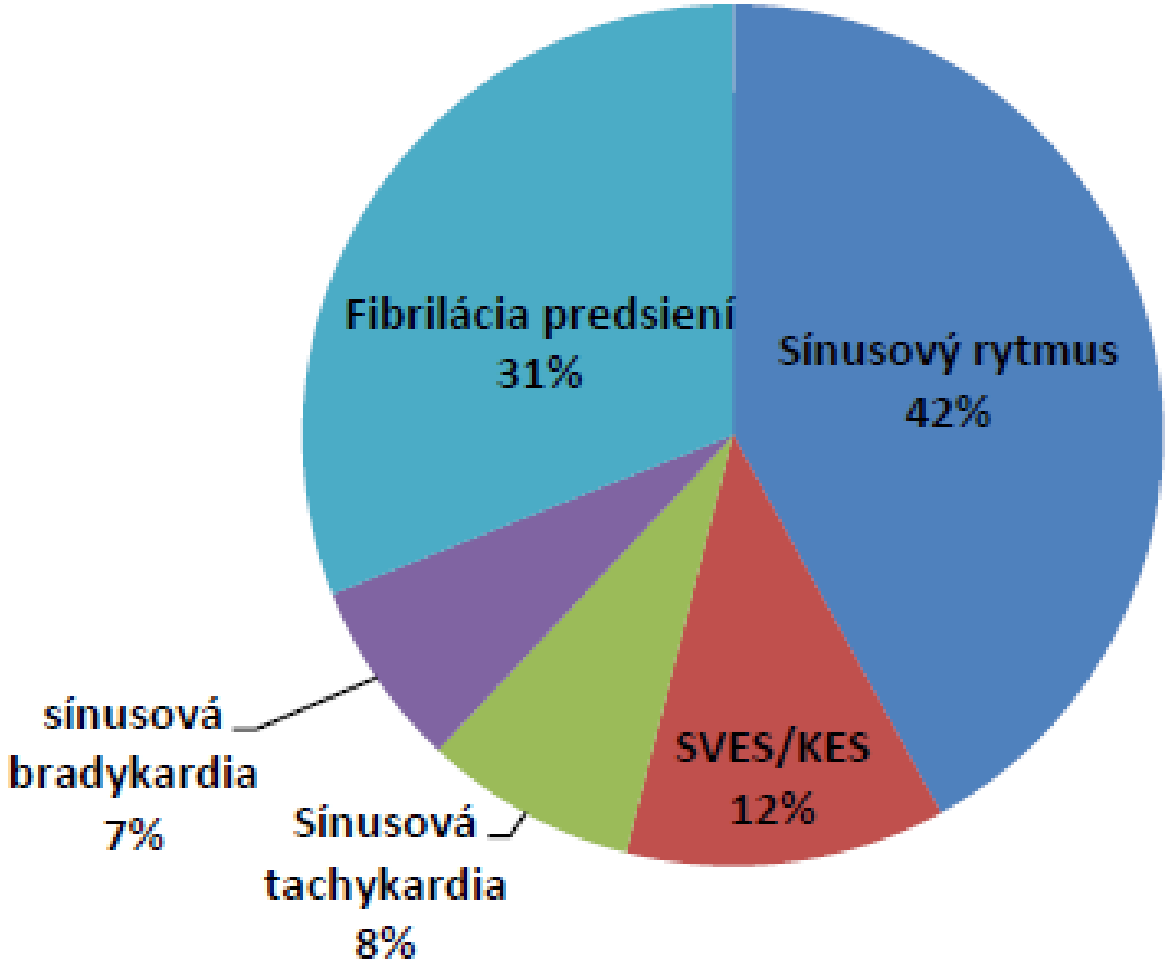
AS-bez FP: Asymptomatický pacient bez FP

As-FP: Asymptomatický pacient s FP%>0.4%

S-bez FP: Symptomatický pacient bez FP **46%**

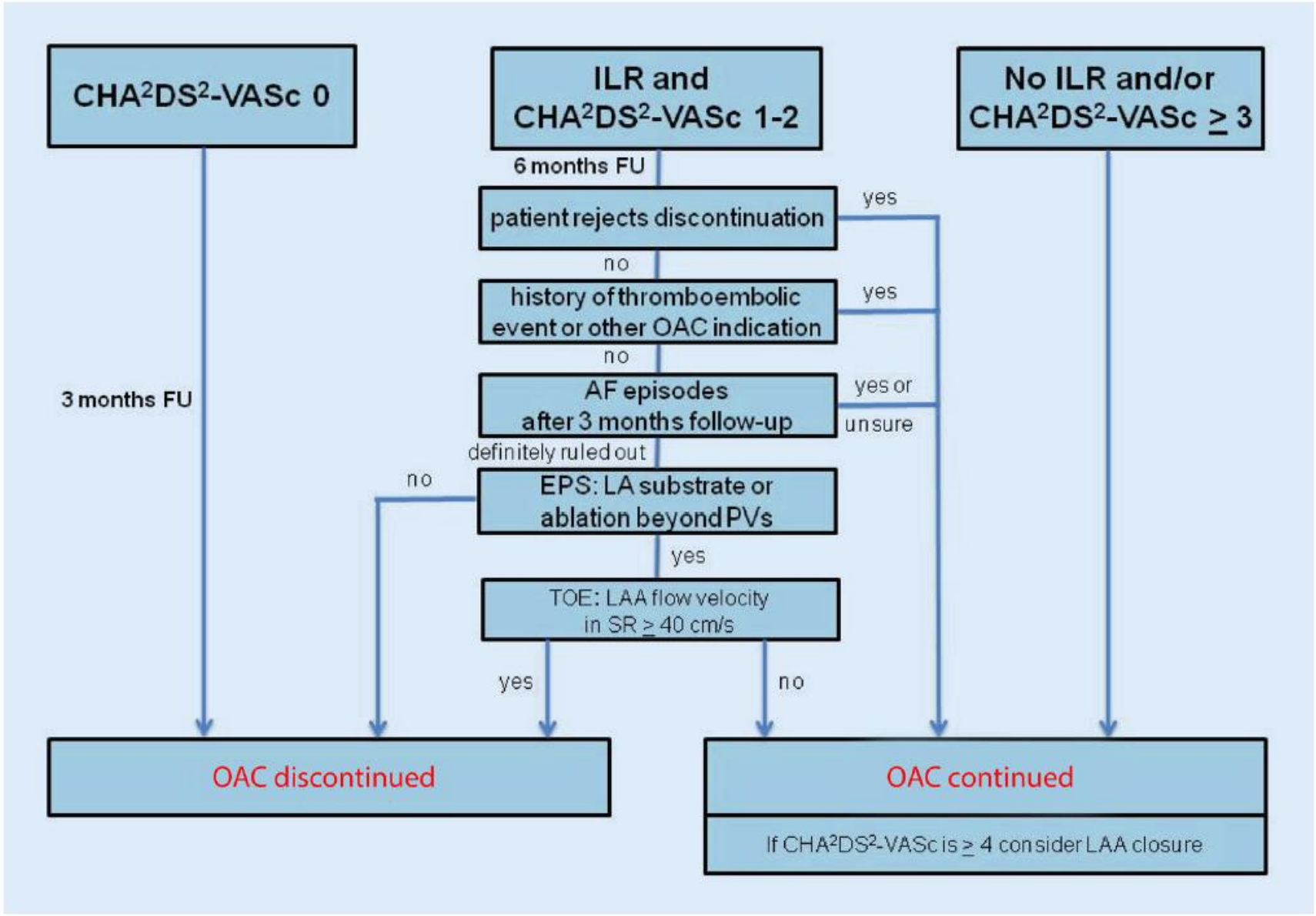
S-FP: Symptomatický pacient s FP>0.4%

EKG v čase symptómov po ABL FP získané kontinuálnym monitorovaním EKG



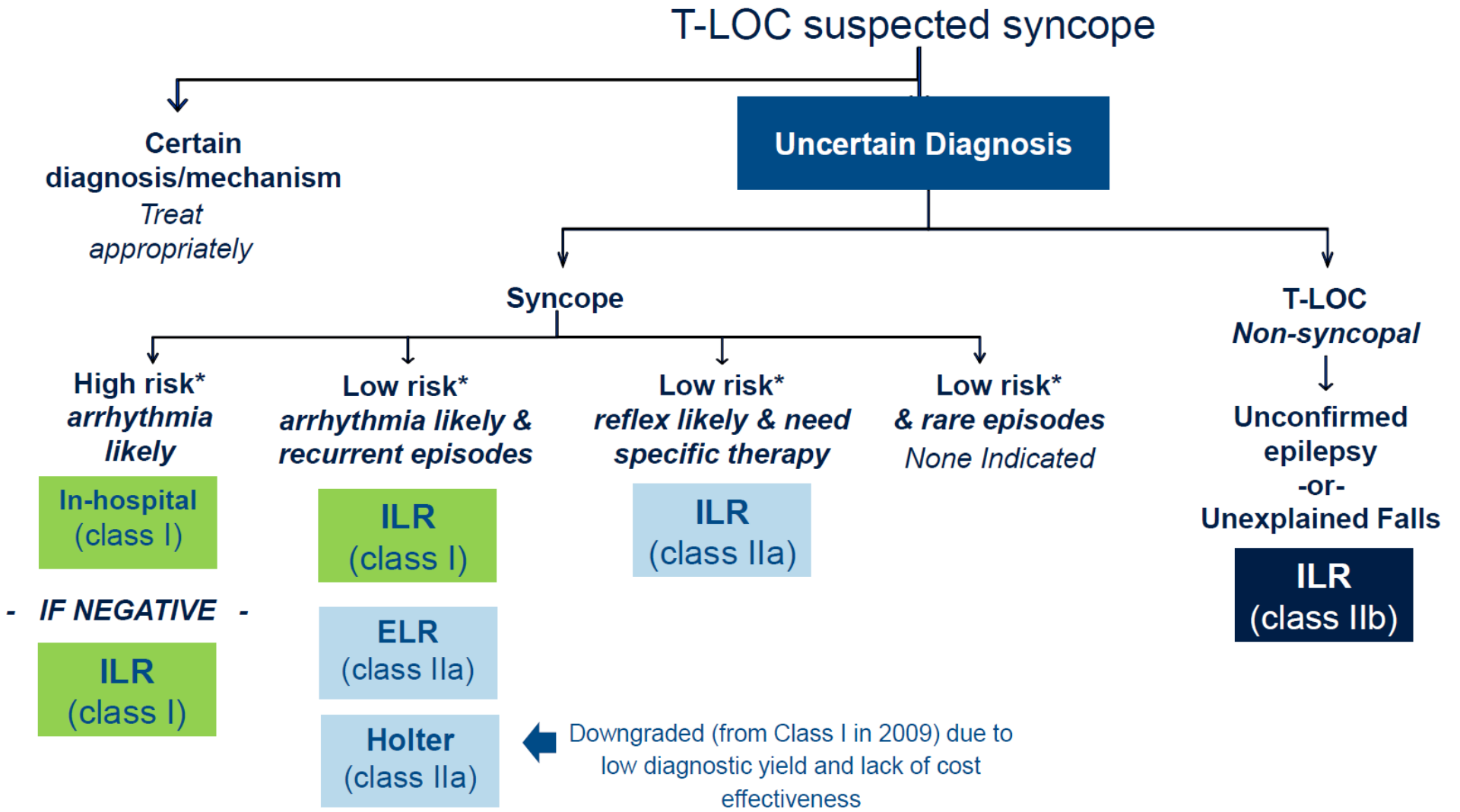
Eur J Cardiothorac Surg. 2011 Aug;40(2):405-11

Protocol for OAT discontinuation after AF ablation



TheDACRIMAStudy. http://www.abstractserver.de/dgk2016/ht/abstracts/P514.htm

T-LOC MONITORING RECOMMENDATIONS



Adapted from Ungar A: ECG monitoring Role in Syncope 2018 ESC Guidelines, EHRA 2018

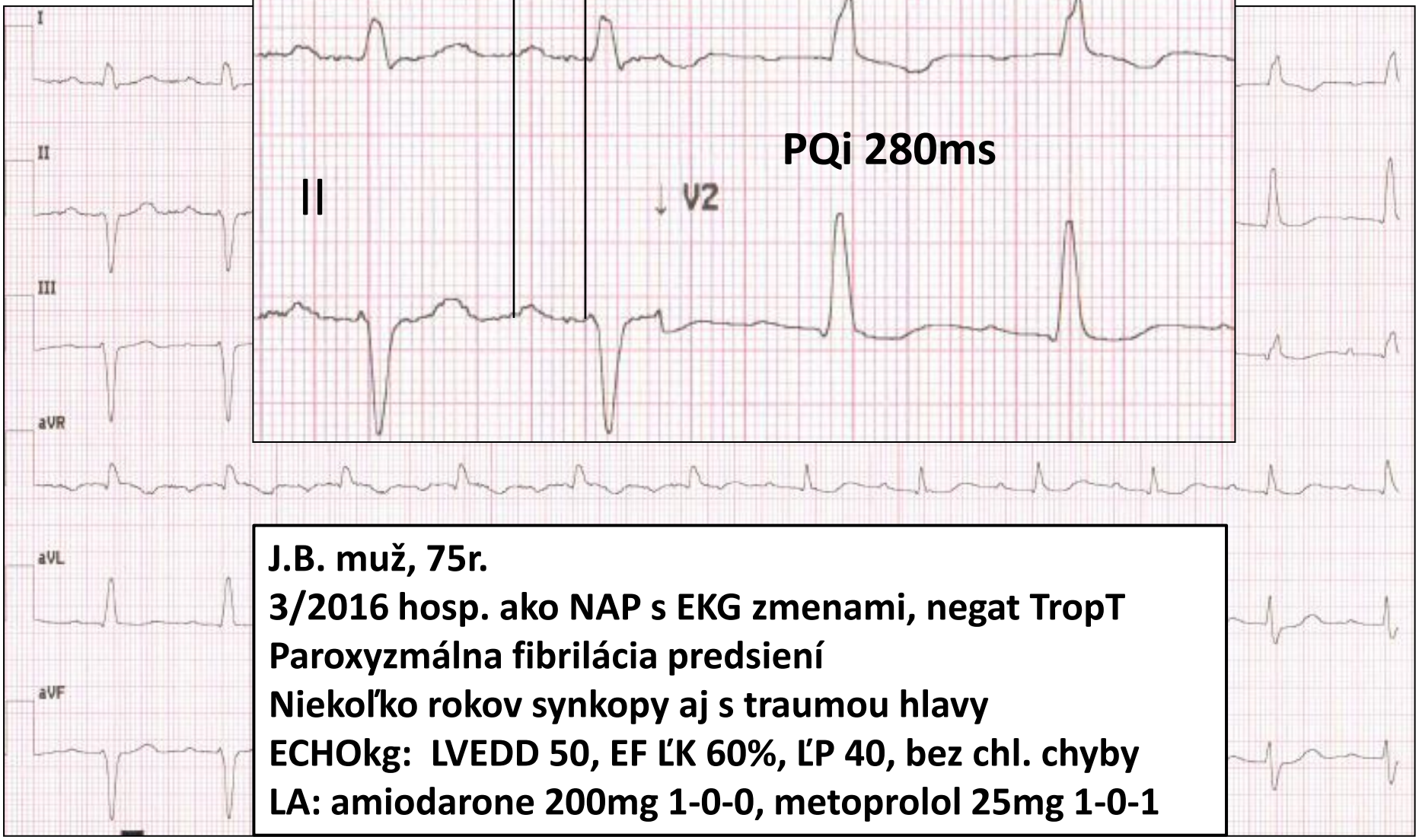
* High Risk & Low Risk Recommendations Summarized on Slides 18 – 19

National prospective and multicenter registry of patients with an ILR implanted in tertiary hospitals in Spain

Patients	655
Age [years]	64.7 ± 16.5
Gender (men)	364 (55.6%)
Left ventricular ejection fraction:	
> 55%	460 (70.2%)
35–55%	75 (11.5%)
< 35%	8 (1.2%)
Electrophysiologic study:	
Normal	245 (37.4%)
Pathologic	45 (6.9%)
Non performed	365 (55.7%)
Carotid sinus massage:	
Performed	330 (50.4%)
Head up tilt test:	
Positive	72 (11.0%)
Negative	139 (21.2%)
Non performed	444 (67.8%)
Cause of implant:	
Recurrent syncope	501 (76.5%)
Single syncope	98 (15.0%)
Presyncope	34 (5.2%)
Others	22 (3.3%)

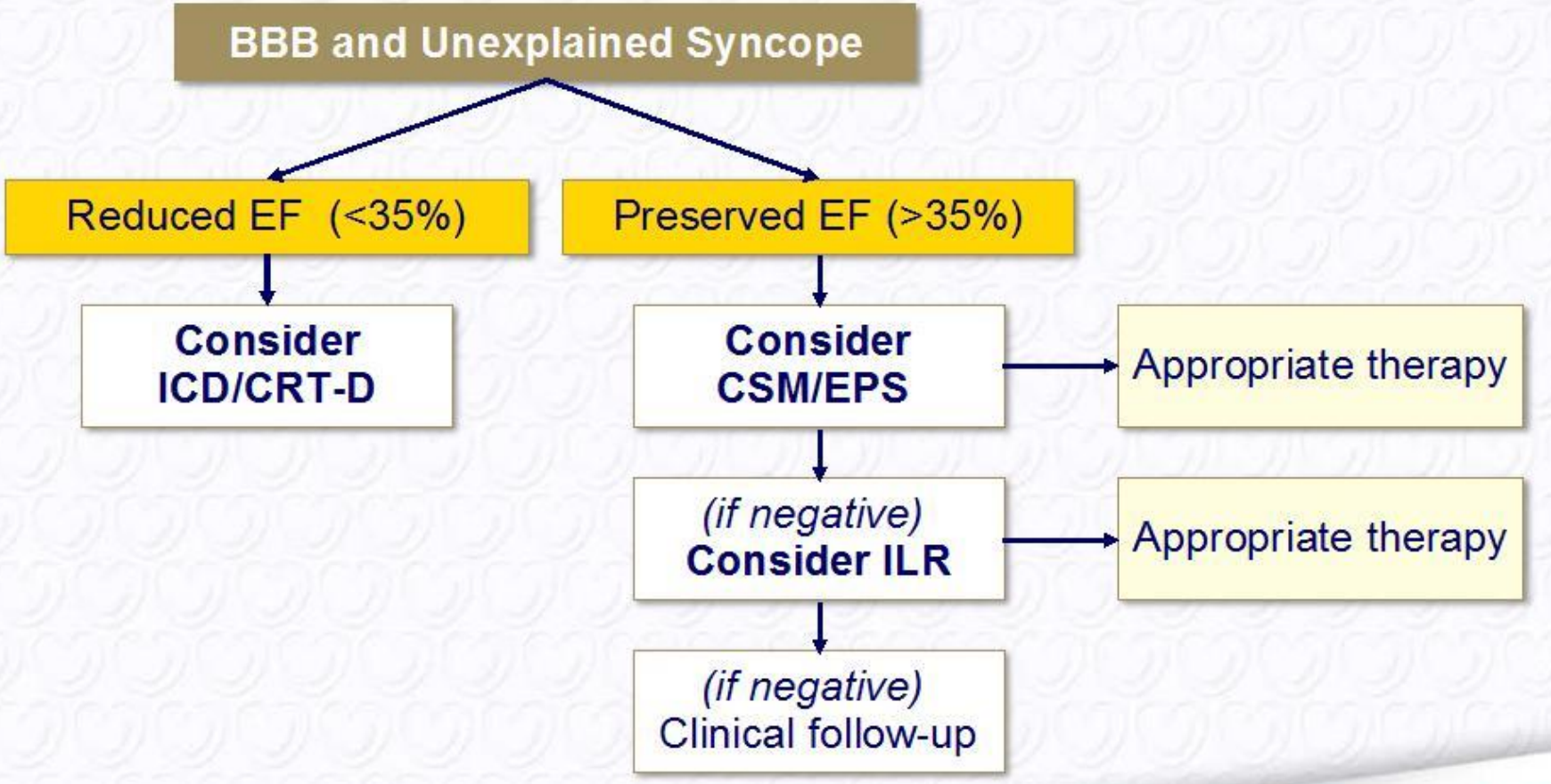
91,5%

Cardiol J 2015; 22, 3: 241–246.

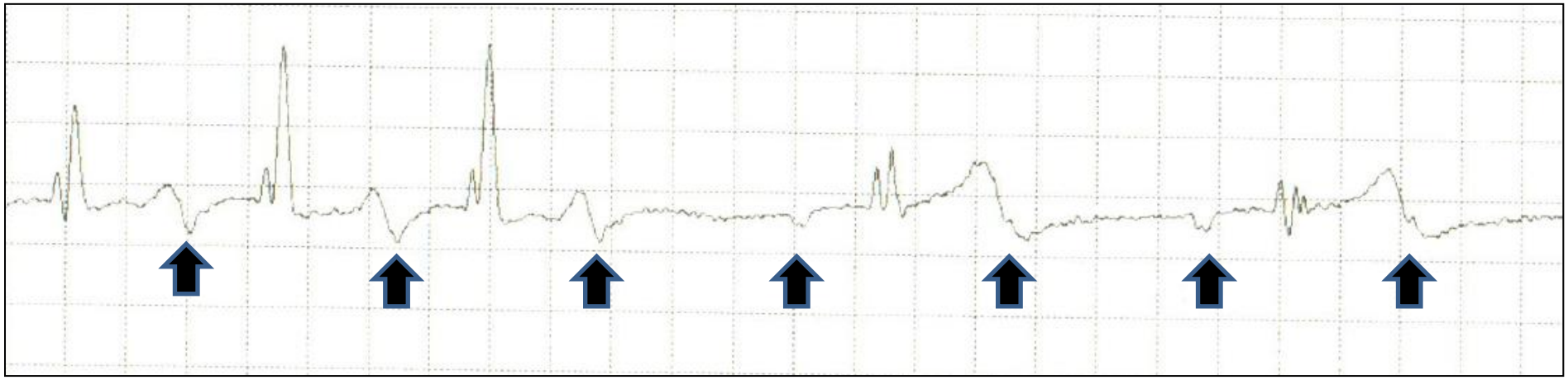


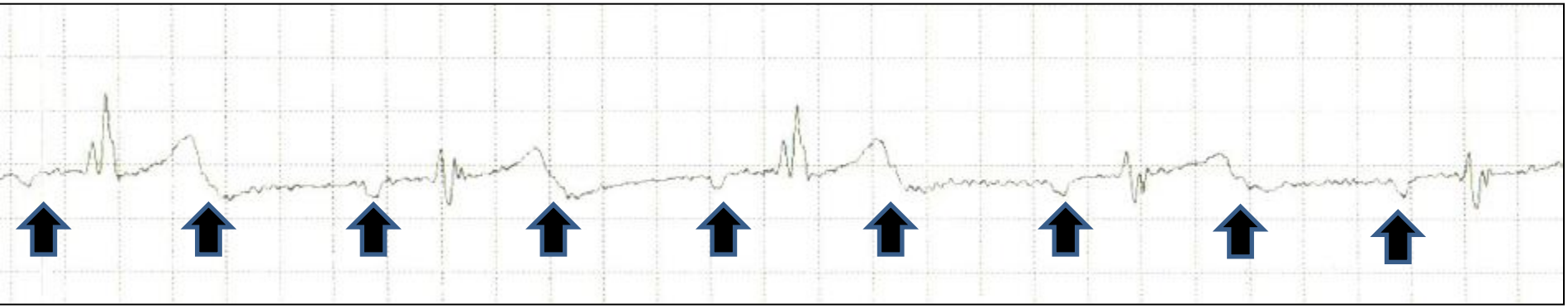
J.B. muž, 75r.
3/2016 hosp. ako NAP s EKG zmenami, negat TropT
Paroxyzmálna fibrilácia predsiení
Niekoľko rokov synkopy aj s traumou hlavy
ECHOkg: LVEDD 50, EF ĽK 60%, ĽP 40, bez chl. chyby
LA: amiodarone 200mg 1-0-0, metoprolol 25mg 1-0-1

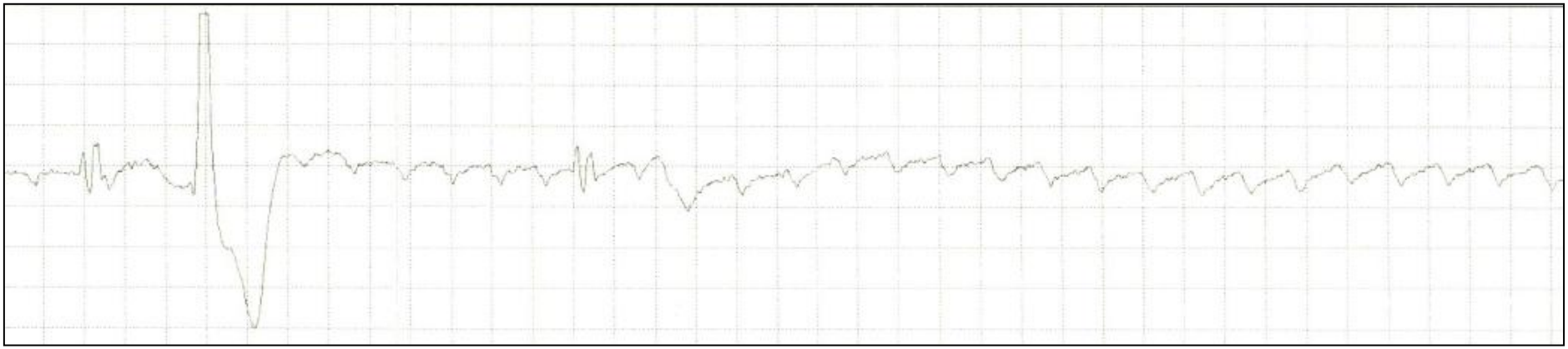
Algorithm for patients with unexplained syncope and BBB

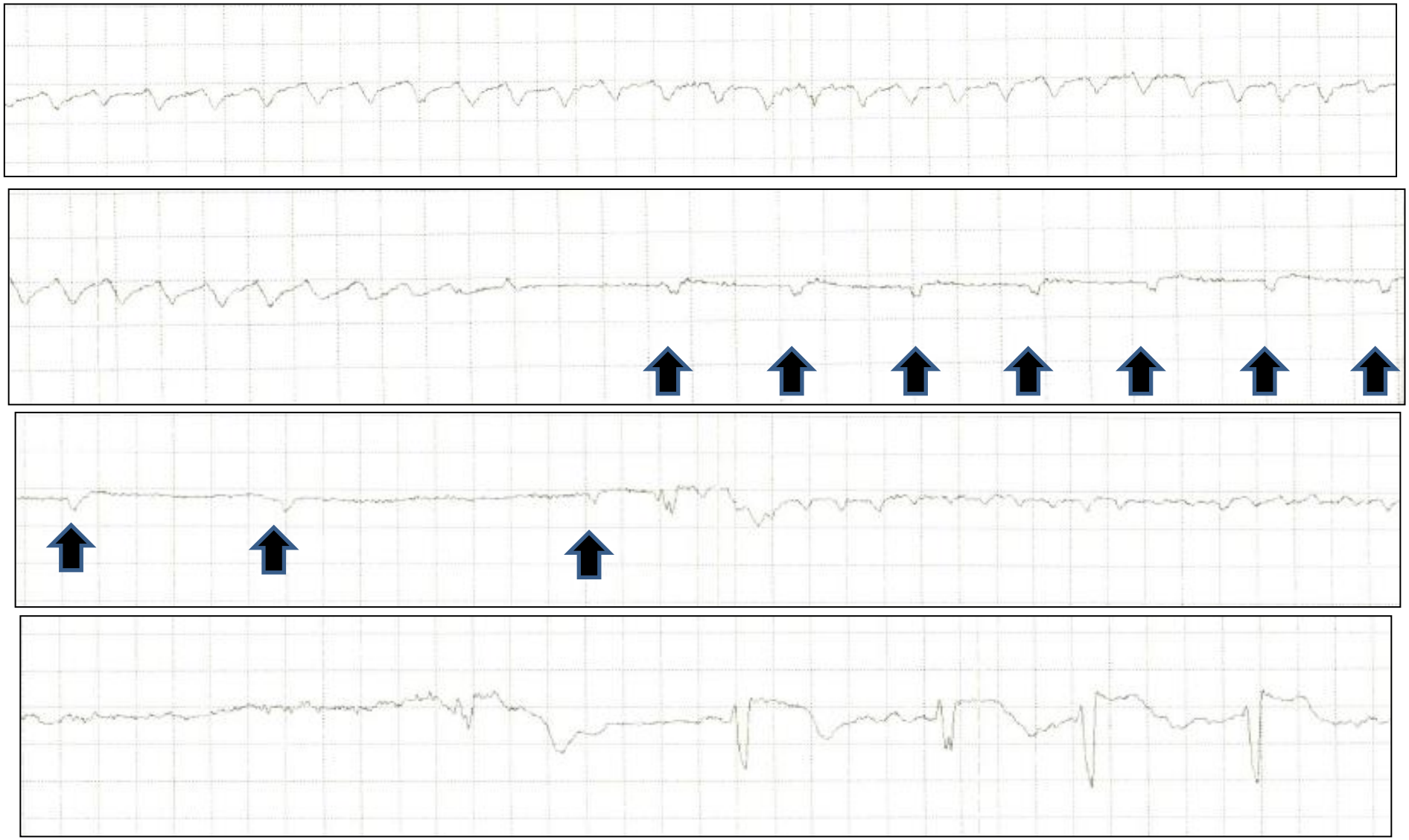


European Heart Journal 2013;34:2281-2329
Europace 2013;15:1070–1118







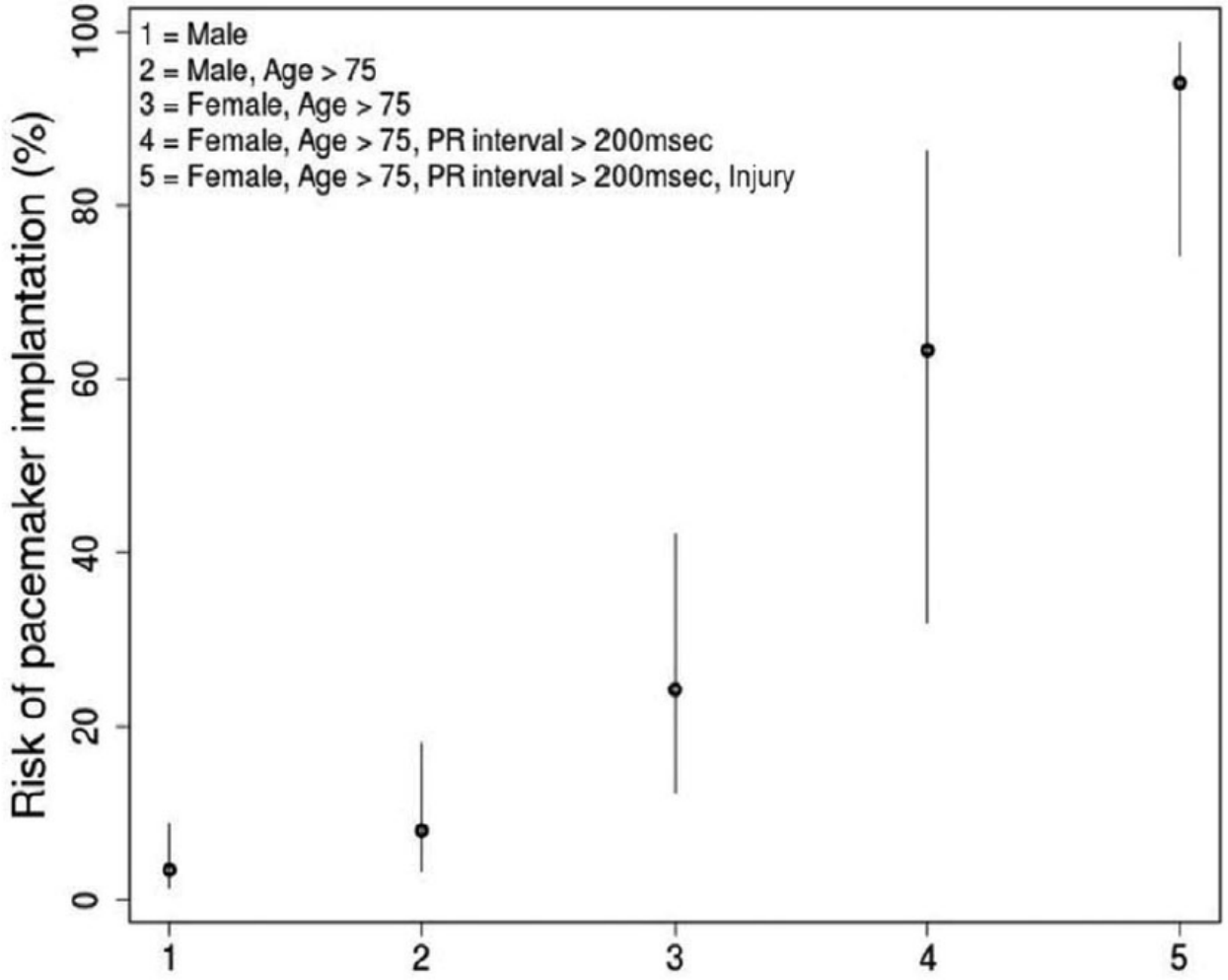


2x synkopa s aktiváciou REVEAL

Synkopa 1 – AVB III.st, komorová asystólia 1 min. 43s.

Synkopa 2 – AVB III.st, komorová asystólia 45s.

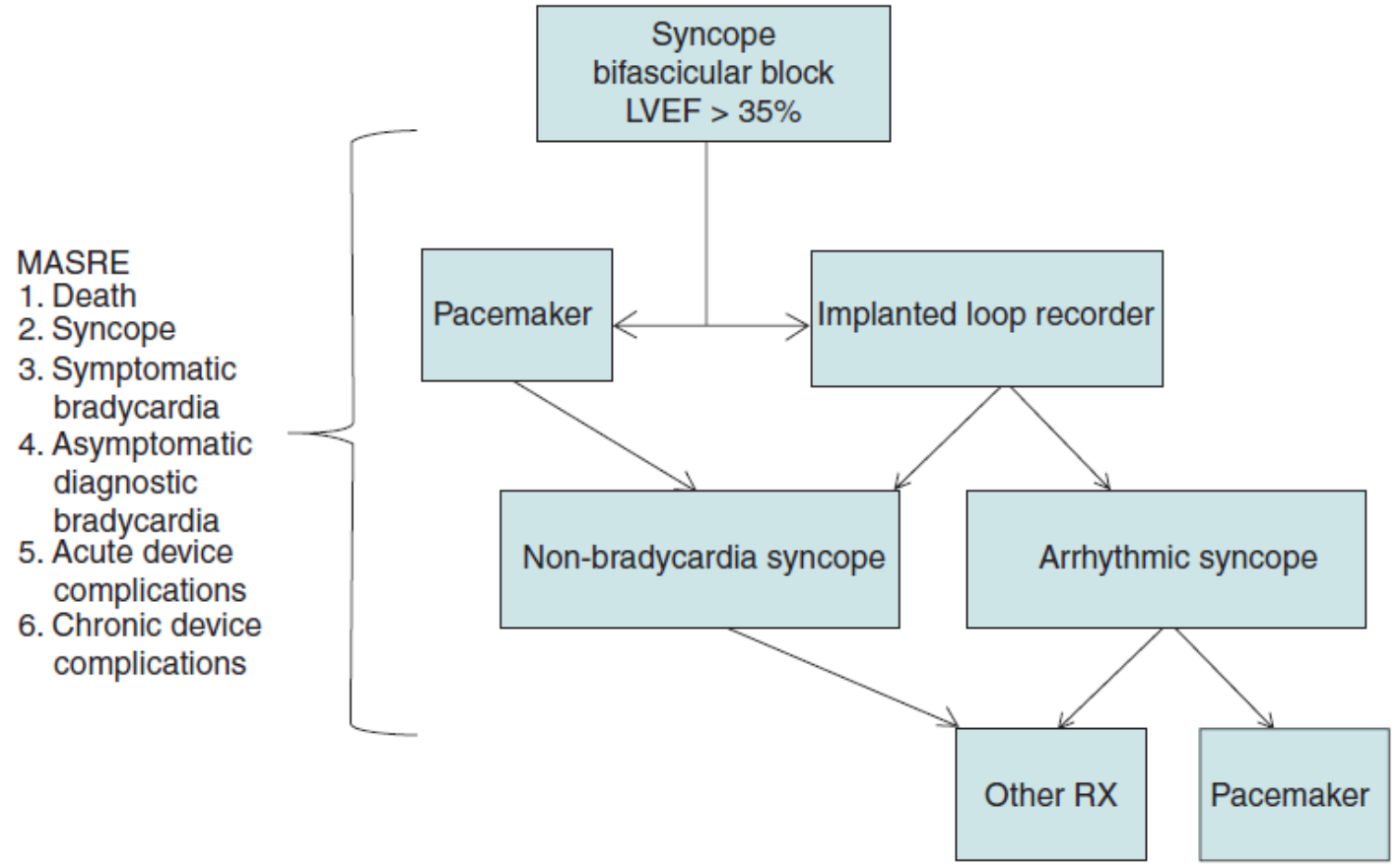
Cumulative risk of PM implantation in 200 patients implanted with ILR for unexplained syncope



PACE 2015; 38:934–941.

Empiric pacemaker compared with a monitoring strategy in patients with syncope and bifascicular conduction block—rationale and design of the Syncope: Pacing or Recording in ThE Later Years (SPRITELY) study

Andrew D. Krahn[1]*, Carlos A. Morillo[2], Teresa Kus[3], Braden Manns[4], Sarah Rose[4], Michele Brignole[5], and Robert S. Sheldon[4]



Europace (2012) 14, 1044–1048

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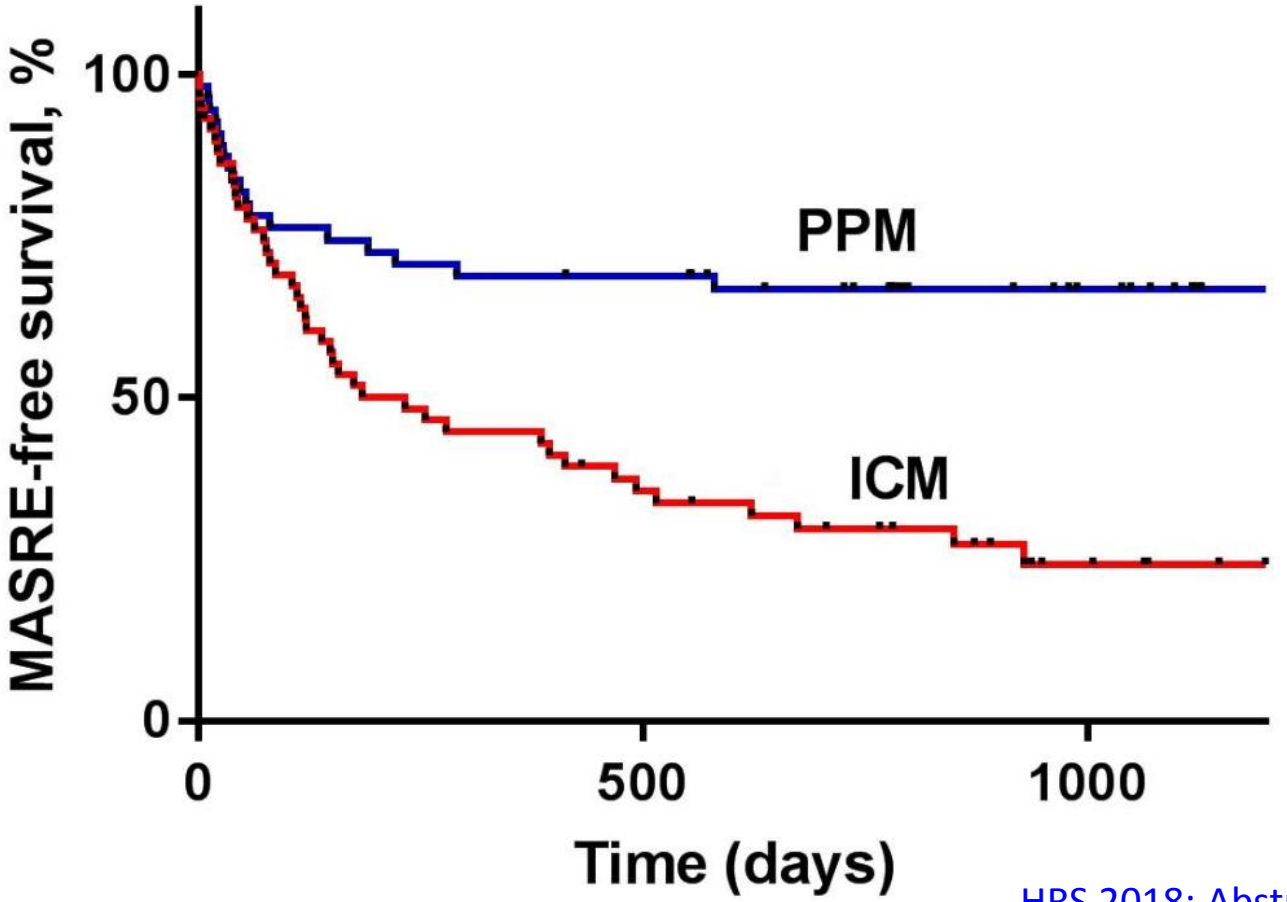


HRS 2018; Abstract B-LBCT01-04.

Typy a racionálne indikácie implantabilných záznamníkov

Ľuboš Urban
NÚSCH a.s., Bratislava

XB4.1	BioMonitor 2	Systém monitorovací kardiologický BioMonitor 2 AF/ 2-S	2 195 €
XB4.1	Confirm	implantabilný EKG slučkový rekordér, rôzne modely	2 195 €
XB4.1	Reveal LINQ	Implantovateľný monitor srdcovej činnosti	2 332 €

XB2.5	DDDR KS	2.000 €
XB2.5.1	DDDR KS MRI komp.	2.300 €

Europace (2017) **0**, 1–8
doi:10.1093/europace/eux187

Clinical impact, safety, and accuracy of the remotely monitored implantable loop recorder Medtronic Reveal LINQ™

Table 2 Therapy established in response to ILR events according to the indication for implantation and in the overall sample

	Atrial fibrillation *N* = 37	Palpitations *N* = 15	Syncope *N* = 52	Ventricular tach. *N* = 26	Stroke *N* = 24	Overall *N* = 154
Anticoagulation	8 (22%)	2 (13%)	4 (8%)	2 (8%)	4 (17%)	20 (13%)
Pacemaker implant	1 (3%)	0	16 (31%)	0	1 (4%)	18 (12%)
EP study/ablation	11 (30%)	5 (33%)	2 (4%)	2 (8%)	2 (8%)	22 (14%)
AA drug therapy change	3 (8%)	3 (20%)	3 (6%)	5 (19%)	0	14 (9%)
Coronary angiogram	0	1 (7%)	0	0	0	1 (0.6%)
ICD implant	0	0	0	1 (4%)	0	1 (0.6%)

AA, antiarrhythmic, EP; eletrophysiological study, ICD; implantable cardioverter defibrillator.

False bradycardia detection for undersensing
False tachycardia detection for oversensing

Europace (2017).

ARTICLE IN PRESS

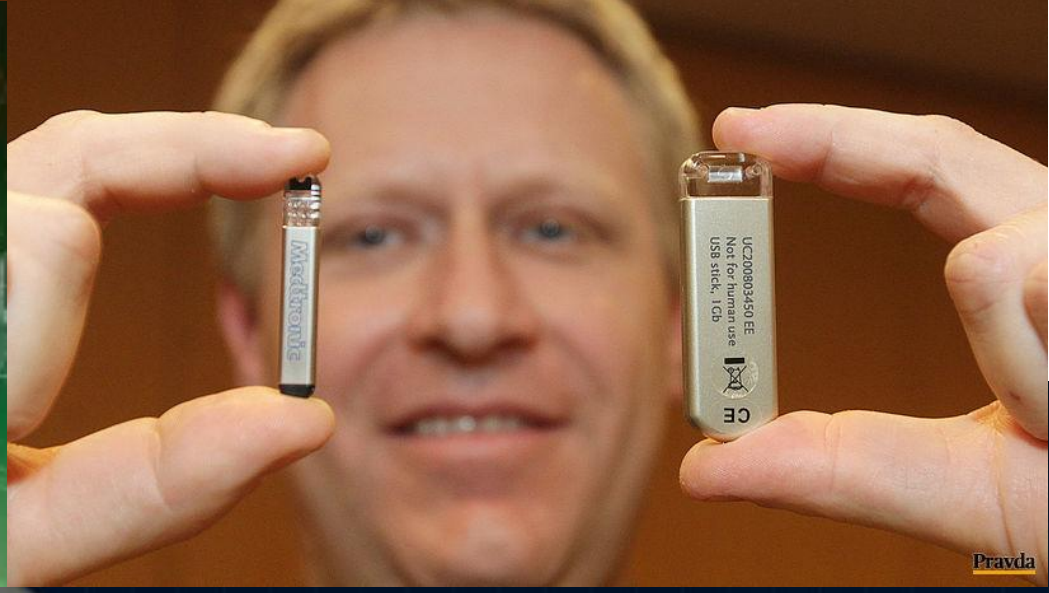
Extended Cardiac Monitoring in Patients With Severe Sleep Apnea and No History of Atrial Fibrillation (The Reveal XT-SA Study)

Implantable Loop Recorder in Inherited Arrhythmia Diseases

A Critical Tool for Symptom Diagnosis and Advanced Risk Stratification

Long-term ECG monitoring using an implantable loop recorder for the detection of atrial fibrillation after cavotricuspid isthmus ablation in patients with atrial flutter

Implantable Loop Recorder Monitoring for Refining Management of Children With Inherited Arrhythmia Syndromes



Ďakujem za pozornosť