10 rokov diaľkového monitorovania prístrojov-čo nám dalo?

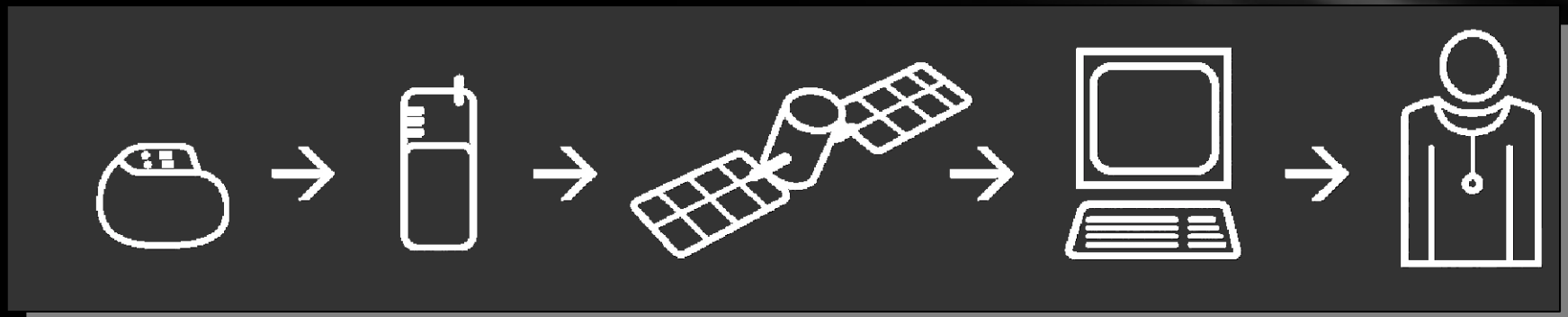
E.Komanová

XIV. české a slovenské sympozium o arytmiích a kardiostimulaci
6 – 8.11.2016, Olomouc

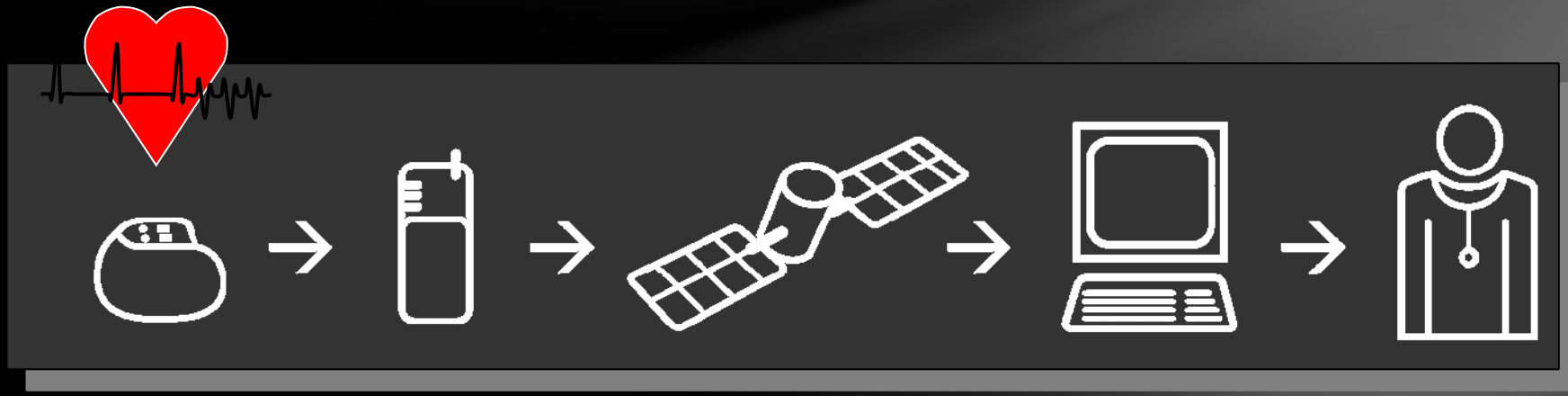
Niečo z histórie...

- 2000 1. implantácia BIOTRONIK Home Monitoring® prístroja
- 2003 1. internetom sprostredkovaný Home Monitoring -systém s novým bezdrôtovým prenosným zariadením
- 2005 1. implantácia ICD so systémom Home monitoring na Slovensku – arytmologické oddelenie VÚSCH Košice
- 2008 štúdia TRUST(redukcia počtu kontrol o 45%)
- 2009 nový BIOTRONIK Home Monitoring® s tzv. systémom semafórových svetiel pre efektívnejšiu a pohodlnejšiu starostlivosť
- 2010 10. výročie monitorovania s novými diagnostickými technológiami pre manažment pacientov s CHSZ

Princíp



Automaticky, bez potreby aktívnej účasti pacienta denne



Automaticky, bez potreby aktívnej účasti pacienta v prípade príhod

Možnosti sledovania

KLINICKÉ PARAMETRE

Všeobecné elektrogram akutálneho rytmu (IEGM), frekvencia srdca

Súvisiace so stimuláciou % RA , RV , CRT stimulácie, AV synchrónie, MS,

Súvisiace s tachyarytmiami epizódy AT/AF, VT/VF, ICD terapie, EKG arytmie

Senzormi sprostredkované údaje pohyb, respirácia, tlak, Optivol

Monitorovnie SZ RR variabilita, fyzická aktivita, Nočná frekvencia srdca, AT/AF, VT/VF, komorová frekvencia počas AT/AF

TECHNICKÉ PARAMETRE

batétria, odpor elektród, amplitúdy P a R vĺn, autocapture

Štúdie

Remote Monitoring Reduces Healthcare Use and Improves Qu

The Evolution o
In

Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the

EuroEco (European Health Economic Trial on Home Monitoring perspective in five
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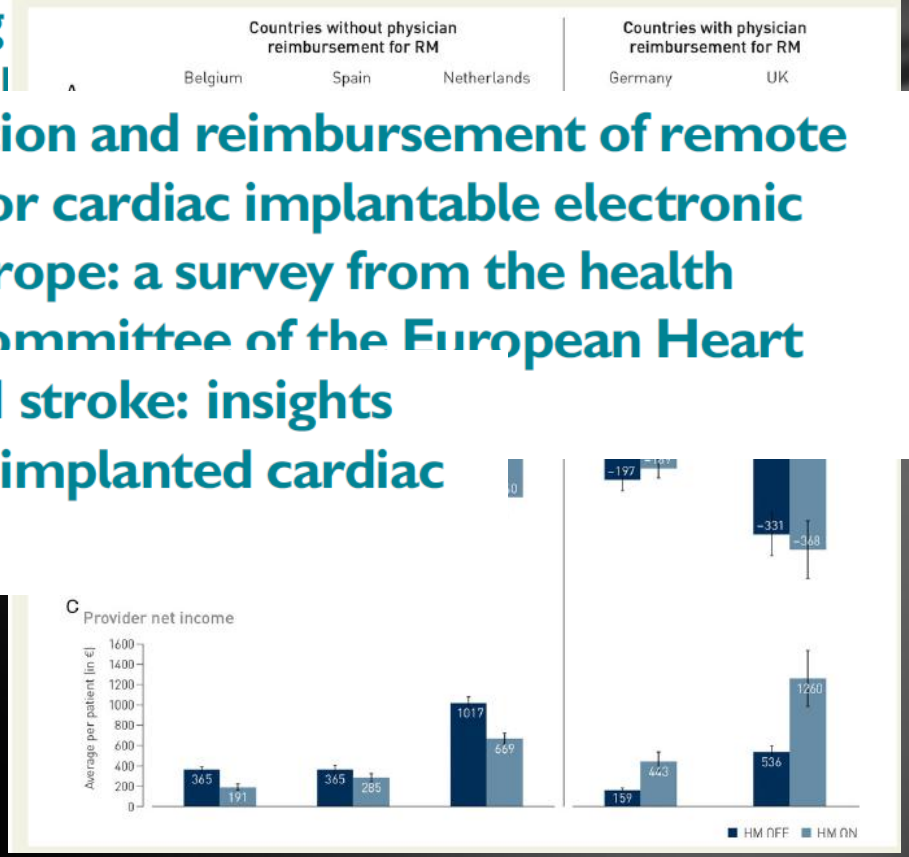
Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart

Subclinical atrial fibrillation and stroke: insights from continuous monitoring by implanted cardiac electronic devices



Prínos monitorovania

- **Redukuje počet ambulantných vyšetrení, plánovaných aj neplánovaných o 38% (1,2)**

(1)Crossley GH. Late breaking clinical trial presented at 59th annual scientific session, American College of Cardiology (ACC), Atlanta GA, Mar 14-16, 2010.,(2) EVOLVO trial

- **Predvída klinicky významné príhody a redukuje čas od príhody ku klinickému rozhodnutiu o 79%** Results of CONNECT trial – 1,997 patients from 136 clinical sites followed for 15 months -- J Am Coll Cardiol Vol. 57, No. 10, 2011.
- **Redukuje priemernú dĺžku hospitalizácie z KV príčin o 18%, s úsporou približne 1.793 US$ na hospitalizáciu** CONNECT trial, J Am Coll Cardiol Vol. 57, No. 10, 2011.
- **Redukuje náklady o 40%** Fauchier et al. PACE 2005; 28: S255-9; Raatikainen MJP et al. Europace 2008;10(10):1145–51.
- **Zlepšuje prežívanie pacientov:** Saxon et al.: Circulation. 2010;120: 2359-2367

Diaľkové monitorovanie

Optimalizácia sledovania

- Redukcia ambulantných vyšetrení
- Efektívne a bezpečné sledovanie funkcie prístroja
- Zlepšenie QoL a komfortu pacienta (zdravotného aj osobného)
- Ovplyvnenie životnosti prístroja
- Redukcia nákladov

Optimalizácia liečby

- Predsieňová fibrilácia
- Srdcové zlyhanie
- Predvídanie hroziacih nežiadúcich účinkov
- Možnosť redukcie hospitalizácií, mortality a morbidity

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.

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

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.

Heart Rhythm, Vol 12, No 7, July 2015

Dostupné monitorovacie systémy

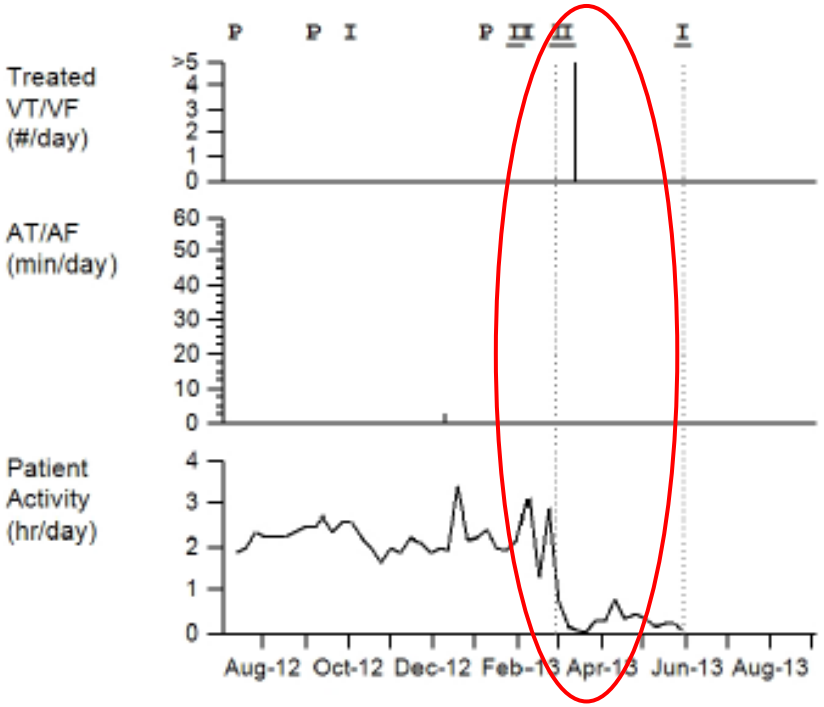
- Biotronik: HOME-MONITORING™
- Medtronic: CARE-LINK™
- St. Jude Medical: MERLIN.NET™
- Sorin: SMARTVIEW™
- Boston Scientific: LATITUDE™

Súčasný stav - Slovensko

Monitorovací systém	NÚSCH	SÚSCH	VÚSCH	Novapharm
Medtronic: CARE-LINK™/CL espres	299	288/53	330/19	88
Biotronik: HOME-MONITORING™	173	35	414/237	N.A.
St. Jude Medical: MERLIN.NET™	0	16	9	N.A.

Clinical Status	Since 27-Feb-2013
Treated	
VF	125
FVT (Off)	
VT	0
AT/AF(Monitor)	
Monitored	
VT (Off)	
VT-NS (>4 beats, >176 bpm)	32
SVT: VT/VF Rx Withheld	0
AT/AF	0
Time in AT/AF	0.0 hr/day (0.0%)
Functional	**Last Week**
Patient Activity	0.1 hr/day

Cardiac Compass Trends (Jul-2012 to May-2013)



Therapy Summary	VT/VF	AT/AF
Pace-Terminated Episodes	1 of 4	0
Shock-Terminated Episodes	109 of 109	0
Total Shocks	109	0
Aborted Charges	16	0

Pacing	(% of Time Since 27-Feb-2013)
AS-VS	2.9%
AS-VP	97.0%
AP-VS	< 0.1%
AP-VP	< 0.1%

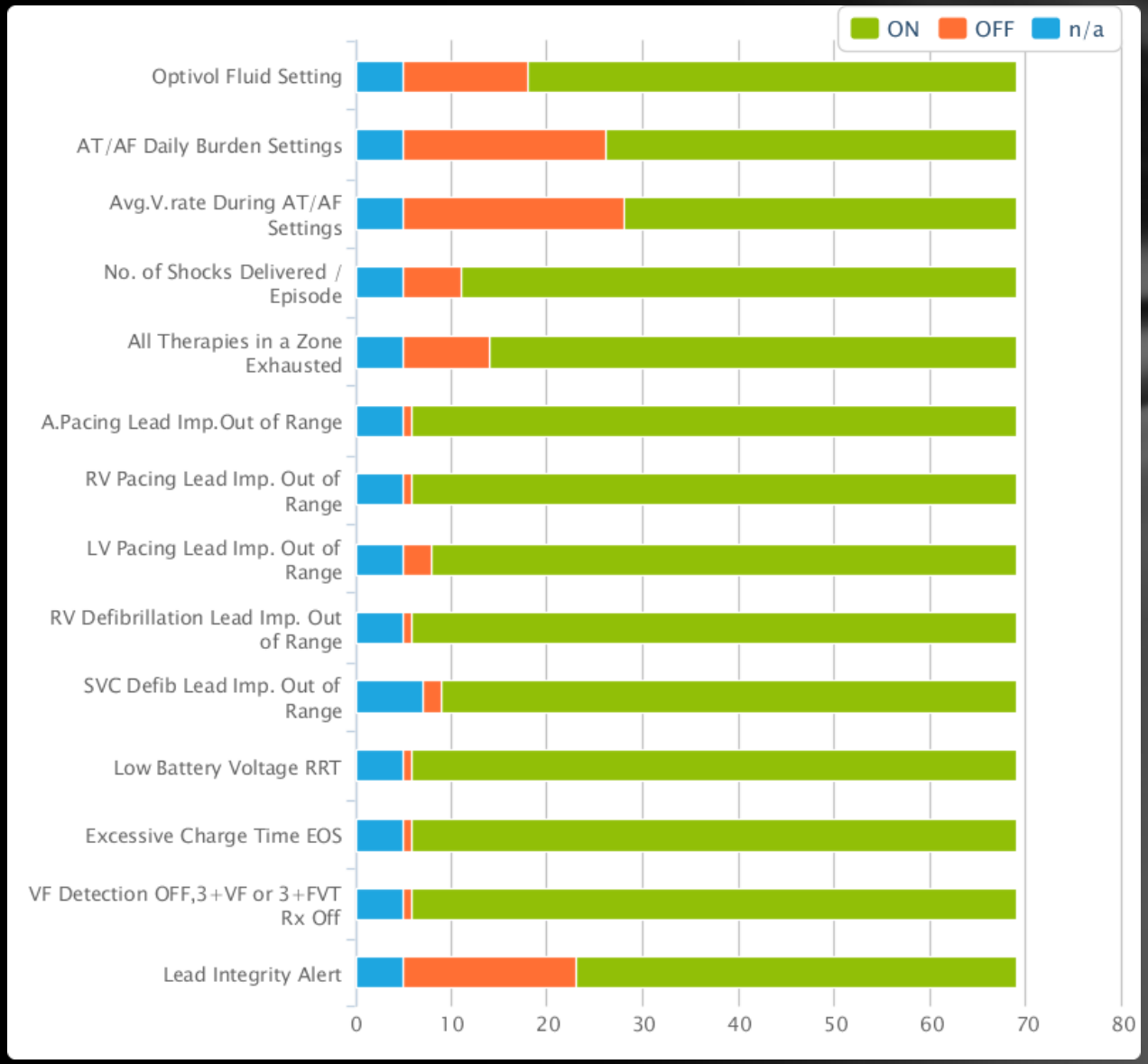
OBSERVATIONS (8)

- RRT (10-Apr-2013): REPLACE DEVICE. Less than 3 months to EOS.
- 109 shocks for VT/VF, 0 failed.
- Alert: RRT, battery voltage low.
- Alert: Possible fluid accumulation: exceeded OptiVol Threshold, 18-May-2013 -- ongoing.
- Patient Activity less than 1 hr/day for 13 weeks.
- Switched to ATP Before Charging due to 1 successes of ATP During Charging.
- Longest ventricular sensing episode since the last session is greater than 60 seconds.
- Ventricular sensing episodes averaged 11 min/day since the last session.

Clinical Management Alerts	Red Alert	Yellow Alert
AT/AF Daily Burden > Threshold	○	◉
Average Ventricular Rate during AT/AF	○	◉
Number of Shocks Delivered in an Episode	○	◉
All Therapies in a Zone Exhausted	◉	○
Optivol Fluid Alert	○	◉

Lead/Device Integrity Alerts	Red Alert	Yellow Alert
VF Detection/Therapy Off	◉	○
Low Battery Voltage Recommended Replacement Time	◉	○
Excessive Charge Time End of Service	◉	○
Right Ventricular Lead Integrity	○	○
Right Ventricular Lead Noise	◉	○
Atrial Pacing Impedance Out of Range	○	◉
Right Ventricular Pacing Impedance Out of Range	◉	○
Left Ventricular Pacing Impedance Out of Range	○	◉
Ventricular Defibrillation Impedance Out of Range	◉	○
SVC (HVX) Defibrillation Impedance Out of Range	◉	○
Non-Programmable Alerts	Red Alert	Yellow Alert
Electrical Reset *	◉	○

Nastavenie alertov u CRT -D



Device status	
Status	OK
Battery status	BOL (EOS · ERI · MOL2 · MOL1 · BOL)
Battery voltage	2.98 V (05-Oct-2011)
Charge time	11.3 s for 40 J (28-Aug-2011 00:00:15)

Findings
No anomalies

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	350 ms	5 * Burst	5 * Ramp	18 J	36 J	6 * 40 J
VT2	OFF	---	---	---	---	---
VF	300 ms	Ramp		18 J	38 J	6 * 40 J

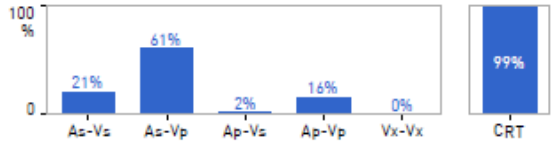
Brady / CRT / AF settings	
Mode	DDDR / BiV-LV
Basic rate / UTR [ppm]	60 / 130
AV delay at 60 ppm / 130 ppm	150 / 120 ms
Mode switching	160 ppm / DDI

Brady leads	RA lead	RV lead	LV lead
Pacing impedance [ohm]	430	443	797
Pacing threshold [V]		---	---
Sensing ampl. mean / min [mV]	1.0 / 0.8	--- / ---	11.5 / 11.5
Programmed [V / ms]	2.8 / 0.5	2.8 / 0.5	2.8 / 0.5

Shock lead	
Daily shock lead imp. [ohm]	46
Last delivered shock imp. [ohm]	---

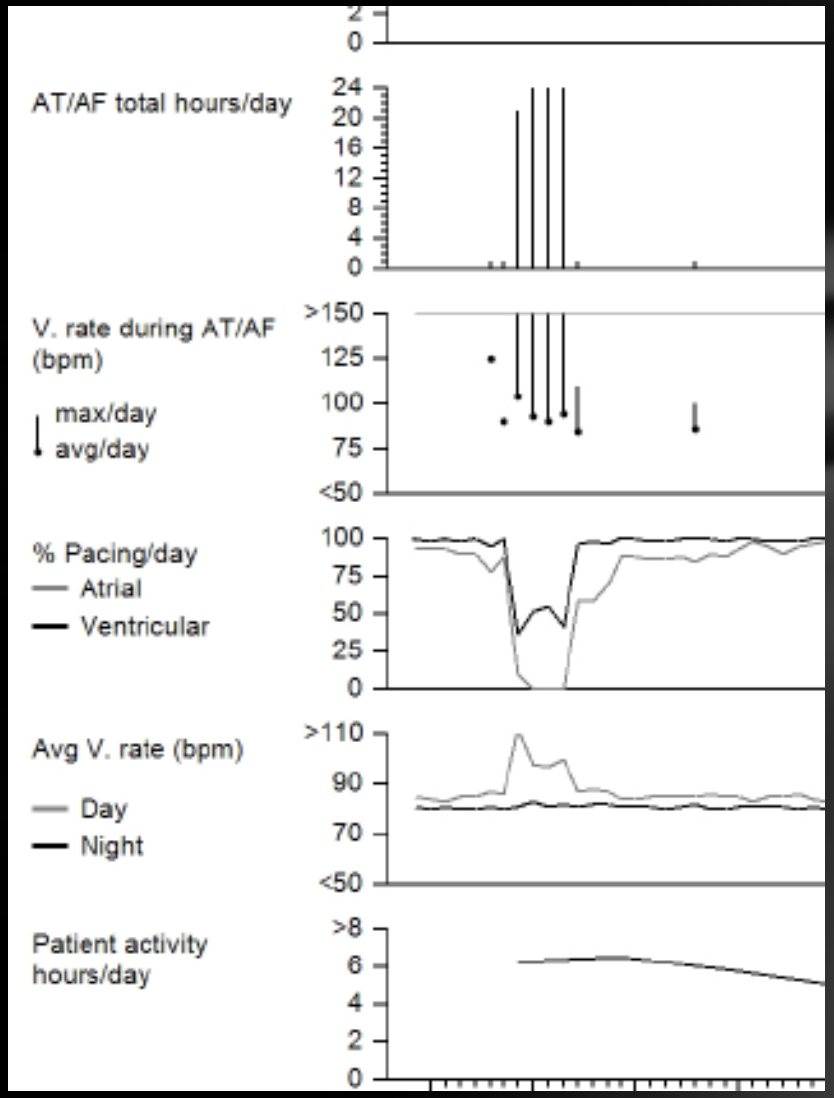
Ven. arrhythmias since 28-Sep-2011	VT1	VT2	VF
Episodes	0	0	0
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	0 / 0 / 0		
Last episode: Atr. monitoring (29-Sep-2011 07:24:30)			

Event episodes since 28-Sep-2011



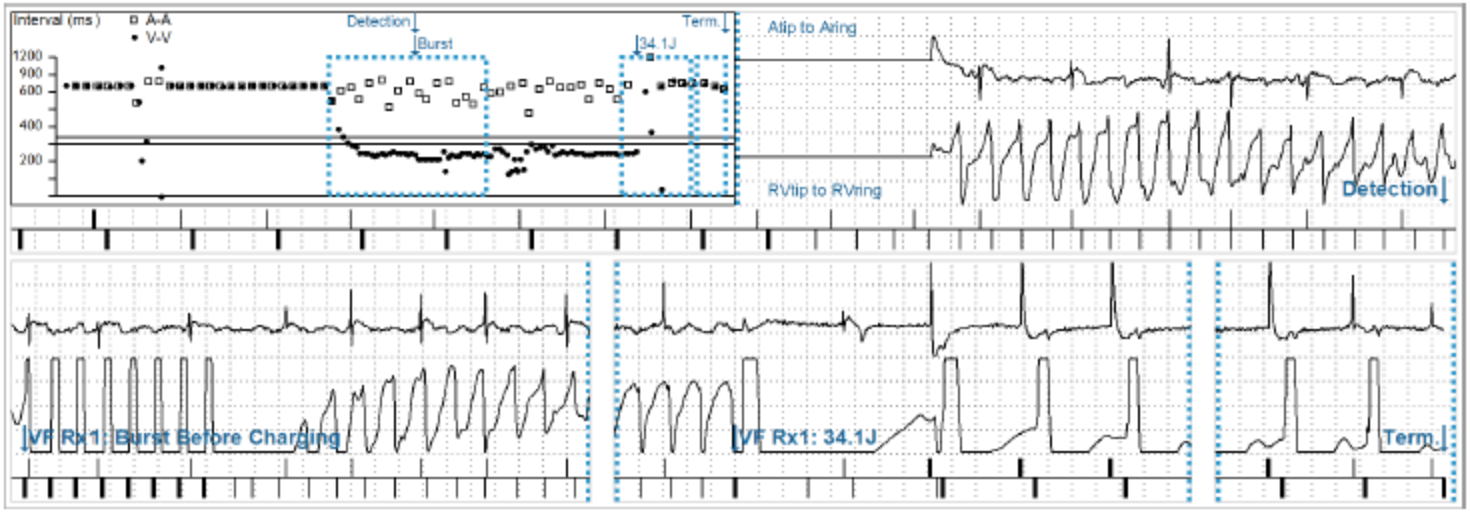
Pacing	
Ap [%]	15%
Vp [%]	76%

Fibrilácia predsienií – CARE-LINK

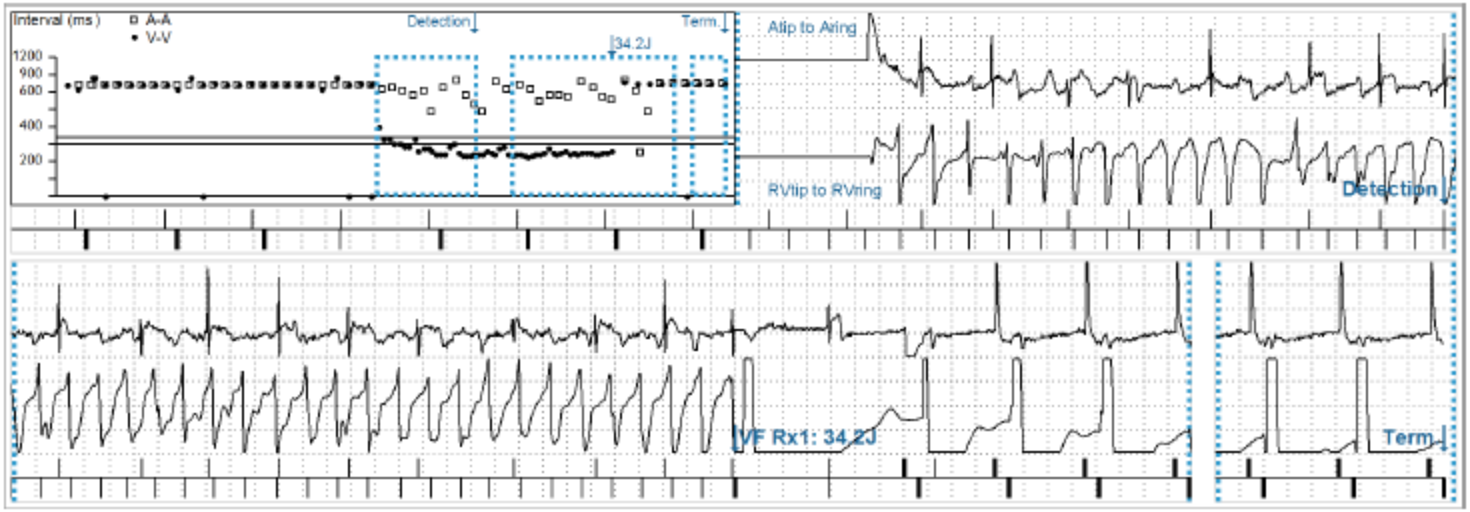


Treated VT/VF Episodes: 100 With EGM: 31

Type	ATP Seq	Shocks	Success	ID#	Date	Time hh:mm	Duration hh:mm:ss	Avg bpm A/V
VF	ATP: 1	35J	Yes	#158	14-Mar-2013	10:58	:20	88/250



VF		35J	Yes	#157	14-Mar-2013	10:07	:14	94/261



Záver

- Diaľkové monitorovanie ICD umožňuje včasnú detekciu závažných aj menej závažných klinických alebo technických príhod u pacientov s TKS, ICD a CRT, a teda aj skorý manažment pacienta.

- Umožňuje lekárovi ako aj pacientovi redukovať počet klinických návštev v prípade optimálnych parametrov prístroja ako aj dobrého klinického stavu pacienta.

- Hradenie ZP predstavuje najväčšiu prekážku v jeho širšom zavádzaní

ĎAKUJEM ZA POZORNOSŤ