

Long-term Cardiac Arrhythmias recorded by an Insertable Loop Recorder in Patients with Depressed Left Ventricular Function after Acute Myocardial Infarction

CARISMA

Cardiac Arrhythmias and Risk Stratification after Myocardial infarction

PE Bloch Thomsen, MD, PhD
Gentofte University Hospital
Copenhagen, Denmark
pebt@geh.regionh.dk

CARISMA investigators

European multicenter, prospective, observational study

Principal investigators: H. Huikuri, Finland, PE Bloch Thomsen, Denmark

P. Raatikainen	University of Oulu, Finland
R.M. Joergensen	University of Copenhagen, Denmark
J. Hartikainen	University of Kuopio, Finland
V. Virtanen	University of Tampere, Finland
J. Boland	Hopital Citadelle, Liège, Belgium
O. Anttonen	Paijat-Hame Hospital, Lahti, Finland
L.A.V. Boersma	St. Antonius Hospital, Nieuwegein, Netherlands
E.S. Platou	University of Oslo, Norway
E. Stoupel	Hopital Erasme, Brussels, Belgium
J. Rokkedal, N. Hoest	Amtssygehuset Glostrup, Denmark

Disclosures

Research grant and speaker fee

- Boston Scientific Guidant
- Medtronic BRC
- St. Jude Medical

CARISMA was sponsored by

- Medtronic Bakken Research Center
- Cambridge Heart Inc

CARISMA – Objective 1

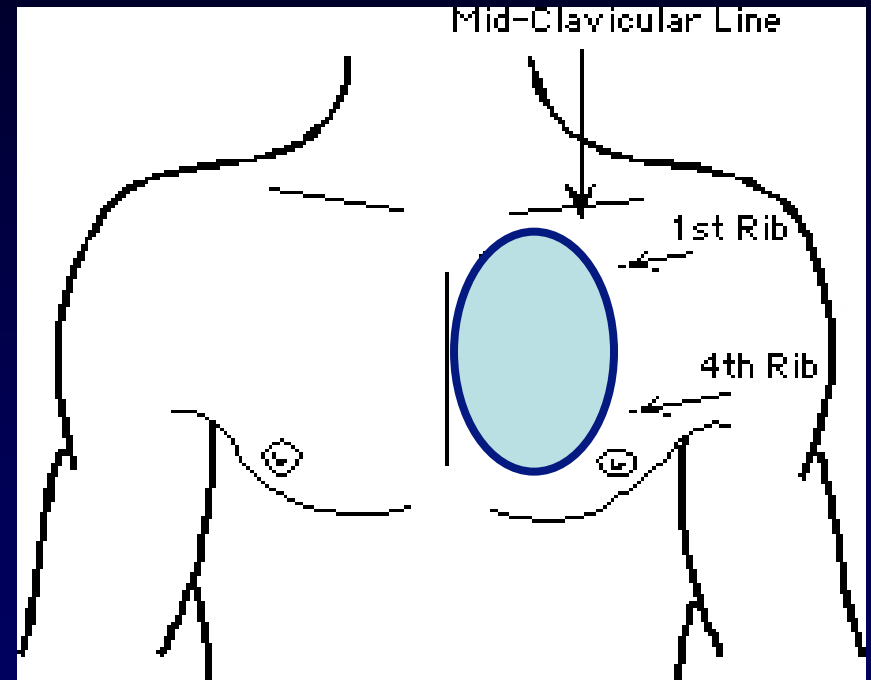
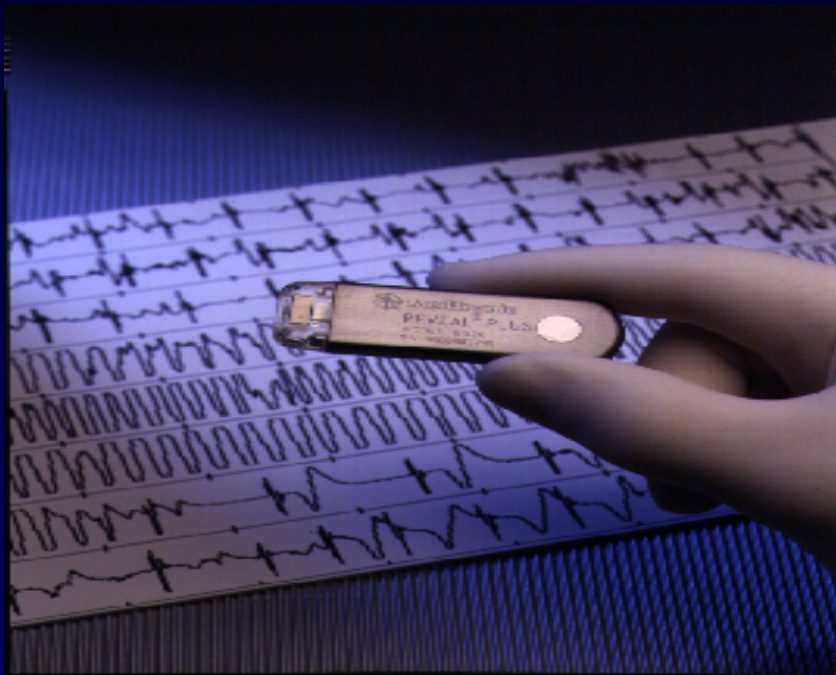
Assess the predictive value of electrophysiologic testing and non-invasive screening tests for life-threatening tachyarrhythmias in patients surviving AMI with $EF \leq 0.40$

(HRS, Hot Line Session, Denver, May 10, 2007)

CARISMA – Objective 2

Document the incidence and assess the prognostic significance of cardiac arrhythmias obtained from an implantable ECG loop recorder

Implantable loop recorder



Weight 1/2 oz, 8 cc. Longevity up to 2 years.

ECG storage 42 min, automatic arrhythmia detection algorithms

Sampling rate 100 Hz

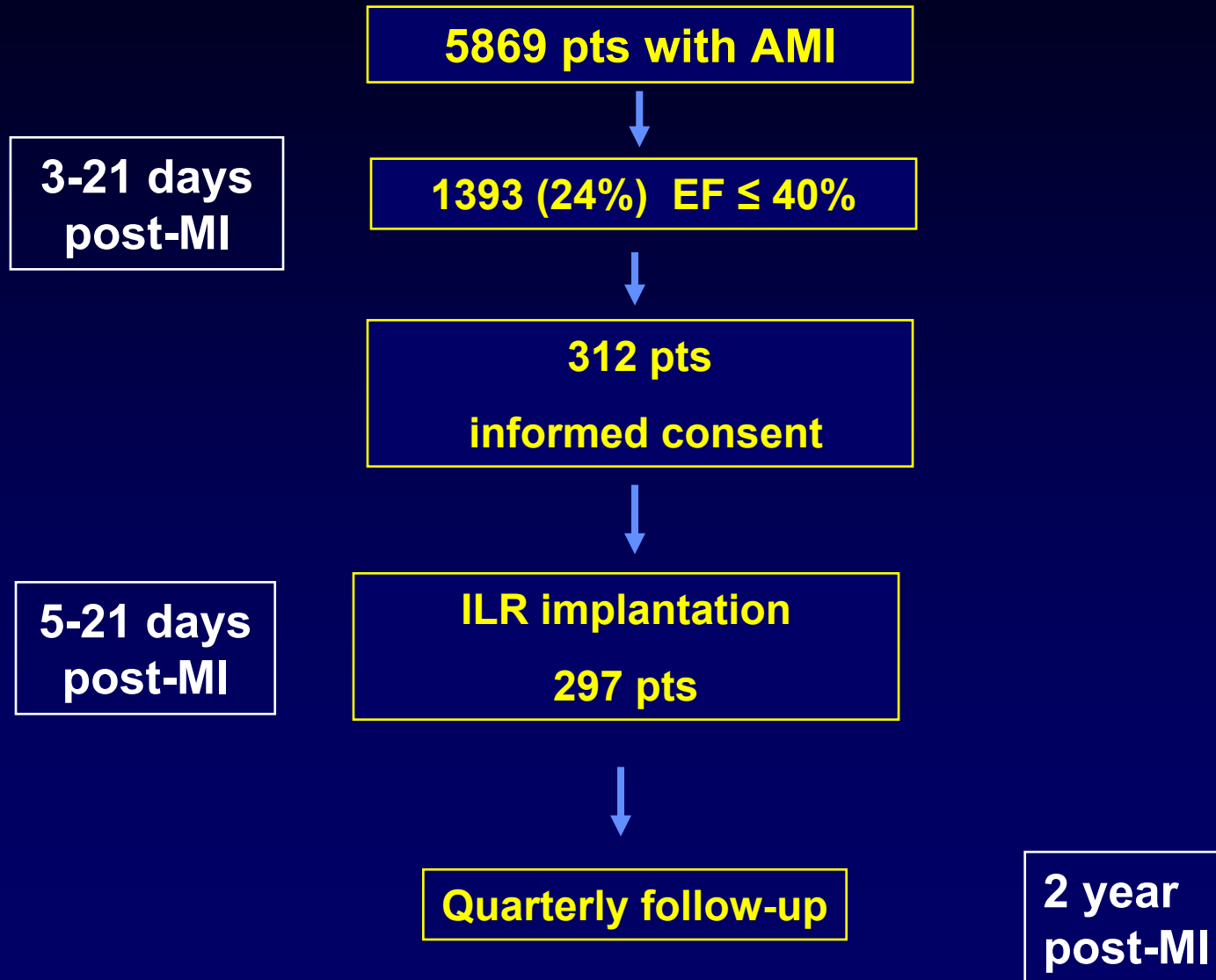
Inclusion criteria

- Patients within 3 to 21 days of AMI
 - + CKMB or Troponin elevation
 - + Typical chest pain or ECG changes
- $EF \leq 40\%$, 2-D echo ($WMI \leq 1.3$)

Exclusion criteria

- Planned CABG/ ICD
- NYHA IV
- Informed consent not obtained

Study design



Patient characteristics

Enrollment: 2002-2005

Baseline

# of pts	312
Gender (men)	77%
Age (years)	65 ± 11
LVEF	31% ± 6
AFib permanent	9%
QRS > 120 ms	15%
Diabetes	20%
Prior MI	37%
Hx of CHF (II-III)	11%

Revascularization

Primary PCI	30%
Thrombolysis	35%

Rx at discharge

ASA	90%
Beta-blockers	96%
ACE / AT II	89%
Statins	82%

Definitions

Pre-specified arrhythmia

Sinus bradycardia	≤ 30 bpm, ≥ 8 s
Sinus arrest	≥ 5 s
AV block (2°, 3°)	≤ 30 bpm, ≥ 8 s
Non-sustained VT	≥ 125 bpm, ≥ 16 beats
Sustained VT	≥ 125 bpm, ≥ 30 s
AFib	≥ 125 bpm

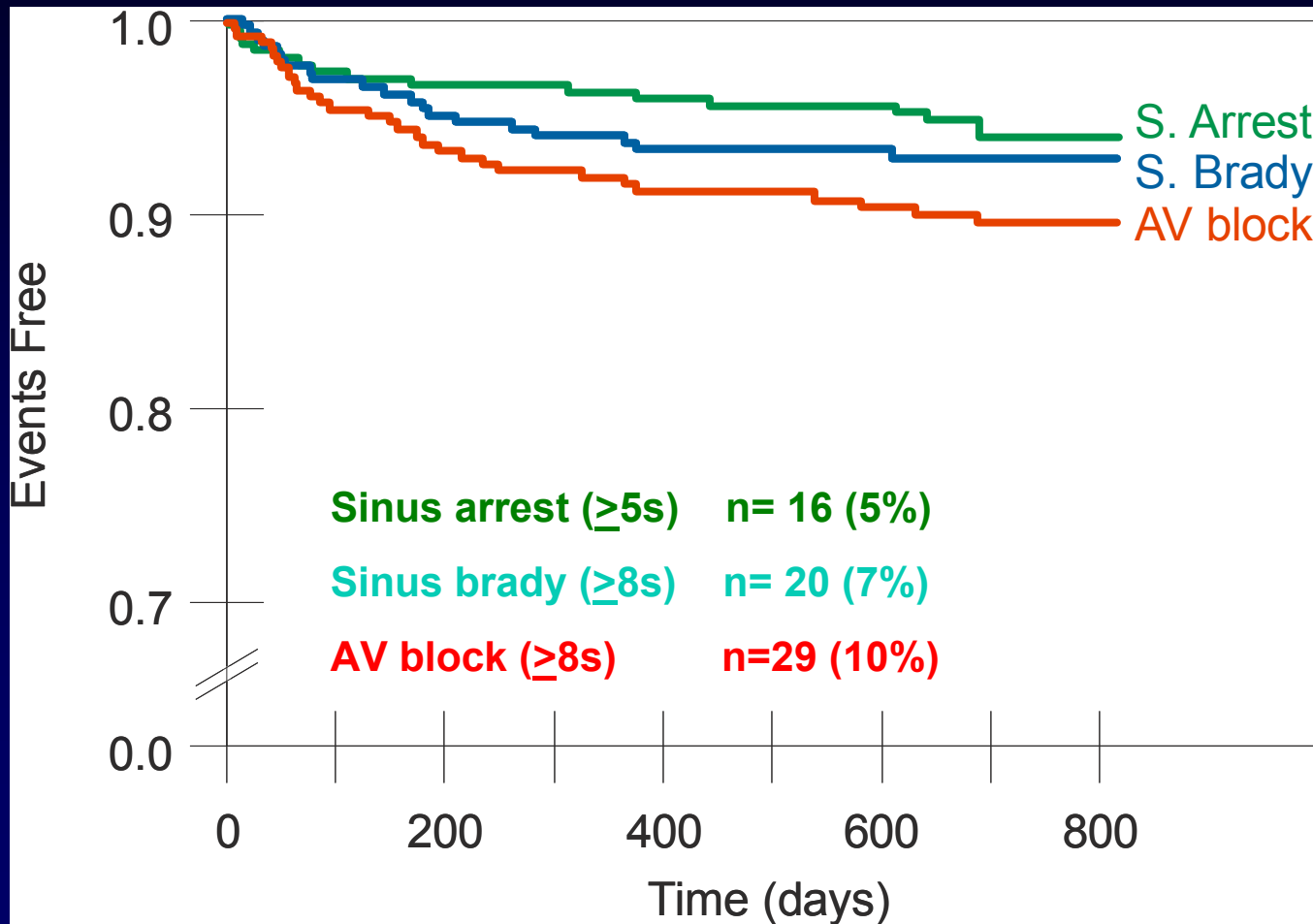
Incidence of arrhythmias recorded by the ILR

Mean follow-up 1.9 years

137 pts (46%) documented at least
one of the pre-specified arrhythmias

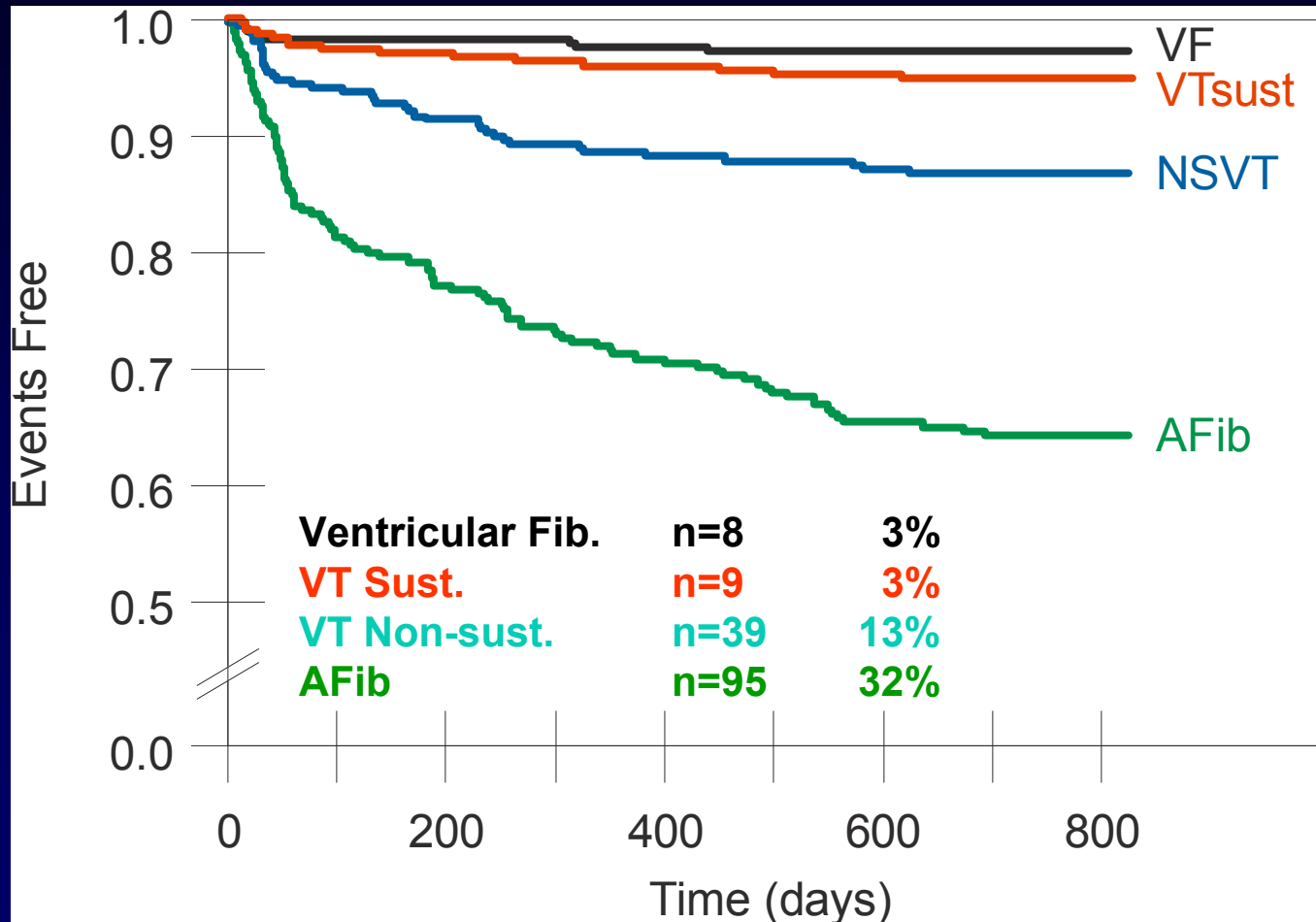
86% were asymptomatic

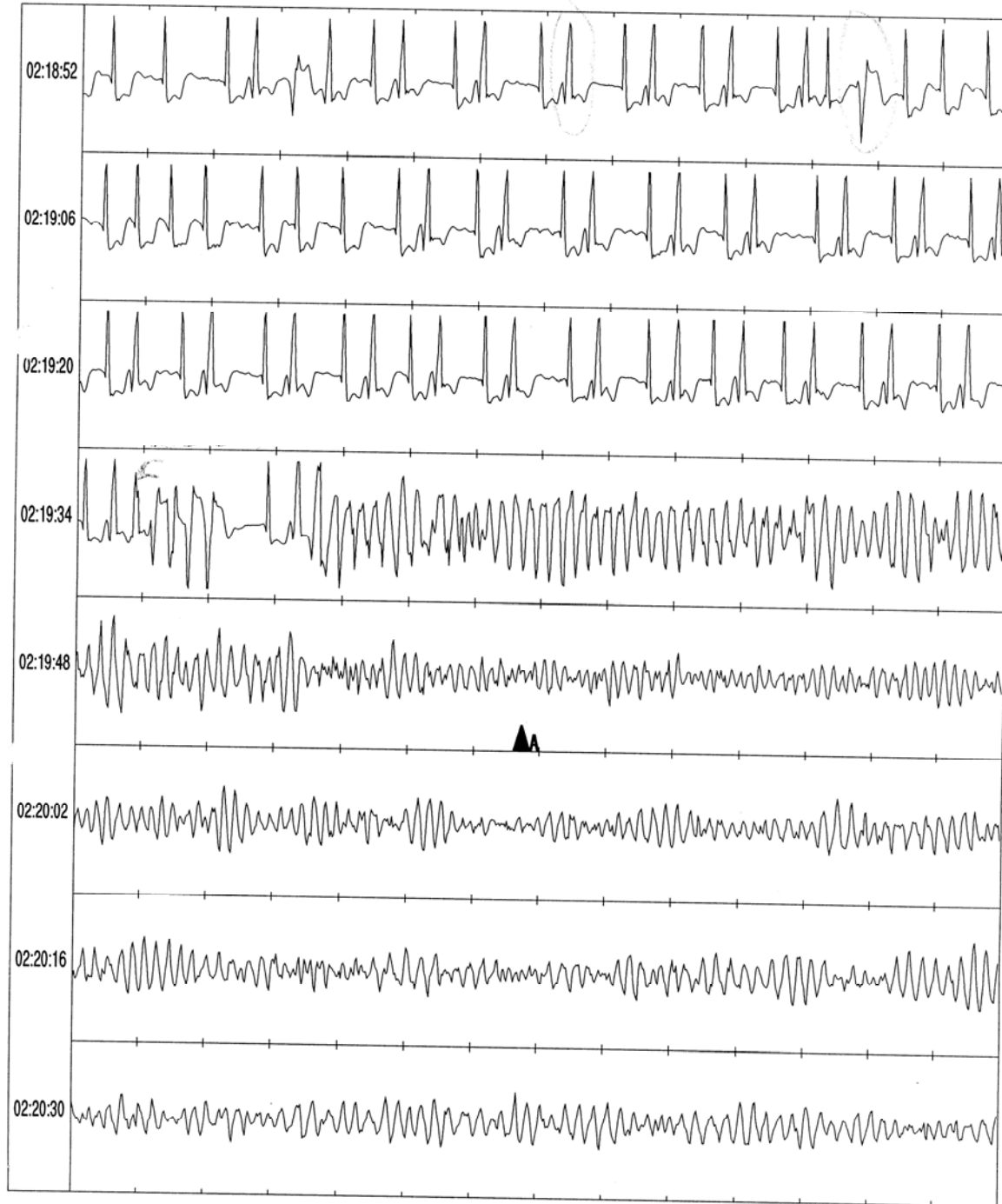
Bradyarrhythmia: Time to first arrhythmia by ILR





Tachyarrhythmia: Time to first arrhythmia by ILR





Conclusion

Incidence of arrhythmias

27% had new onset atrial fibrillation

17% had high degree AV block or
sinus bradyarrhythmia

17% had non-sust VT or VT/VF

Univariate analysis

Predictors of cardiac death

N = 25 (9%)

	HR	p-value
AV block < 30 bpm	7.0	0.0004
Sinus brady < 30 bpm	5.8	0.004
Non sustained VT	3.4	0.025

Multivariate analysis

High-degree AV block was the only independent predictor of cardiac death

HR 4.8 [2.0-11.5] $p < 0.001$

Pre-specified arrhythmias were included as time dependent covariates in a multivariate Cox model.

Summary

CARISMA is the first study to report on long term arrhythmias and prognostics by an implantable loop recorder in patients surviving an AMI with reduced left ventricular function

Conclusion

High-degree AV block
was the only independent predictor of
cardiac death

Future directions

The insertable ECG loop recorder is a diagnostic tool that should be considered to guide medical and device therapy in patients surviving myocardial infarction

BACK UP slides

Limitations

The CARISMA study was an observational study not designed to answer the question whether an ICD is a clinical tool that should be implanted in future post MI patients with reduced left ventricular function

Device implants

57 patients received ICD

5 of the 9 pts with sust V T on ILR

11 of the 39 pts disclosing non-sust VT

22 patients received pacemaker

13 pts disclosed bradyarrhythmias on ILR

Dying with the ILR

	# of pts	
Cardiac death	25	
Dying with ILR	16	
VT/VF	8	(1/7)
Bradycardia	5	
No recordings	3	

Device implants

57 patients received ICD

45 primary prophylaxis

12 secondary prophylaxis

22 patients received pacemaker

Study Design

AMI

**3-21 days
post-MI**

**1393 (24%) / 5869
screened with EF \leq 40%**

LVEF > 40%
→

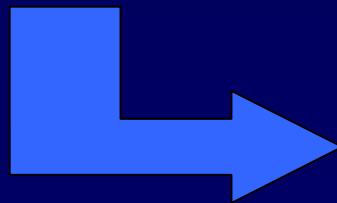
**312 (22%) patients
Informed consent**

**5-21 days
post-MI**

**ILR implantation
297 patients**

**6 weeks
post-MI**

**2 year
post-MI**

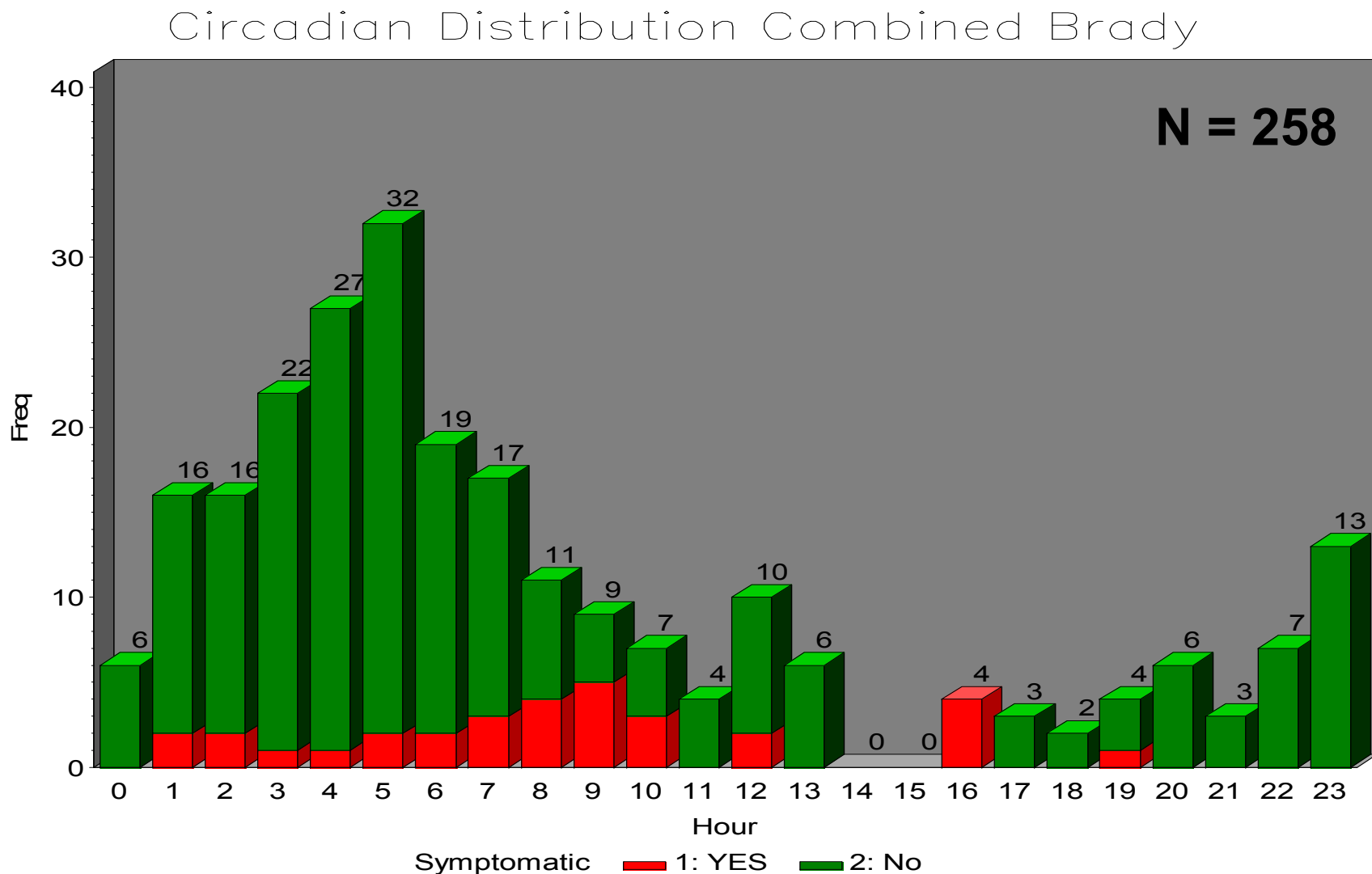


- 1. EP study**
- 2. Exercise test**
- 3. 24-hr Holter**
- 4. T-wave alternans**
- 5. SAECG**
- 6. 12-lead ECG**

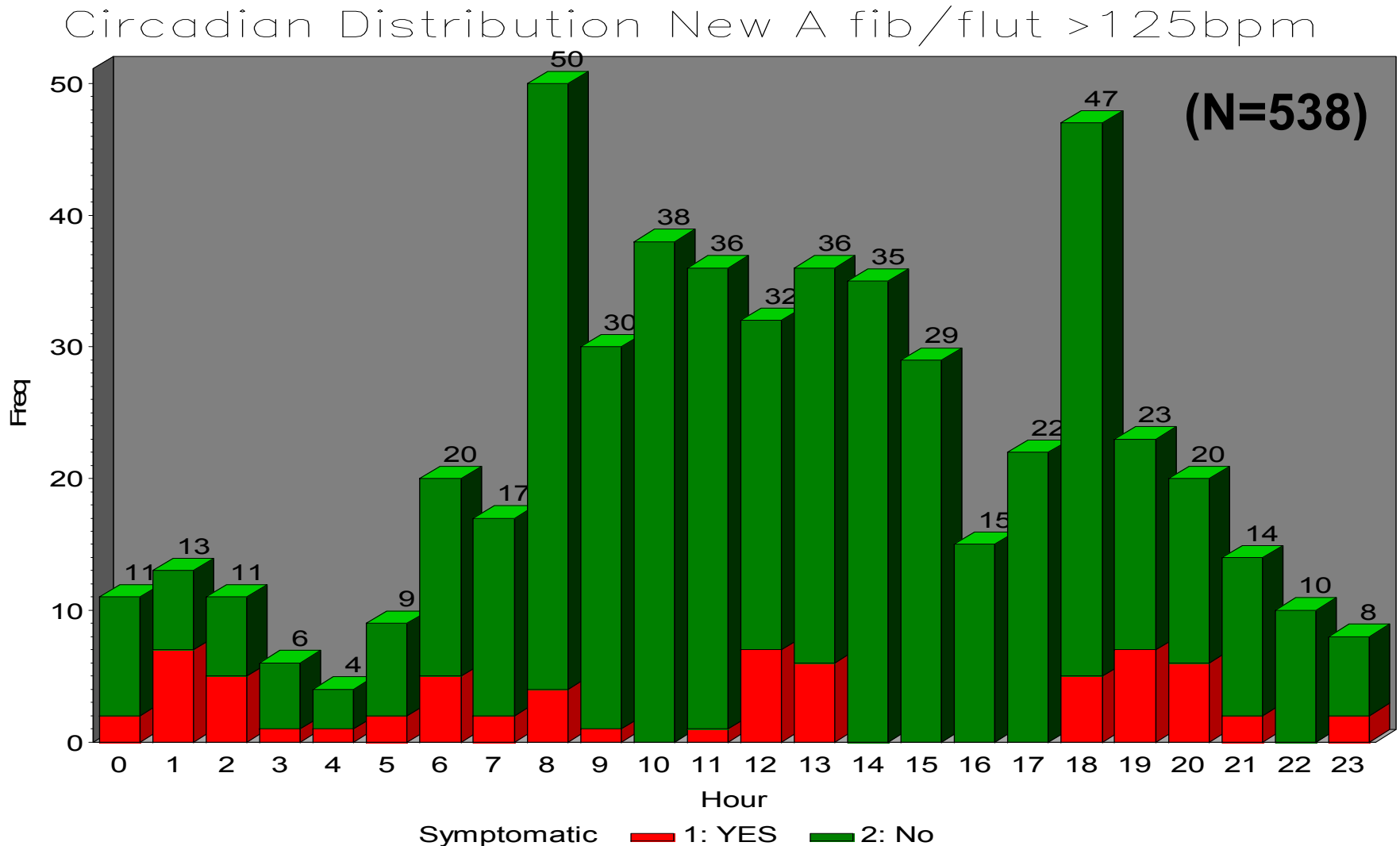
**Quarterly
follow-ups**

Circadian distribution of bradyarrhythmias

N =

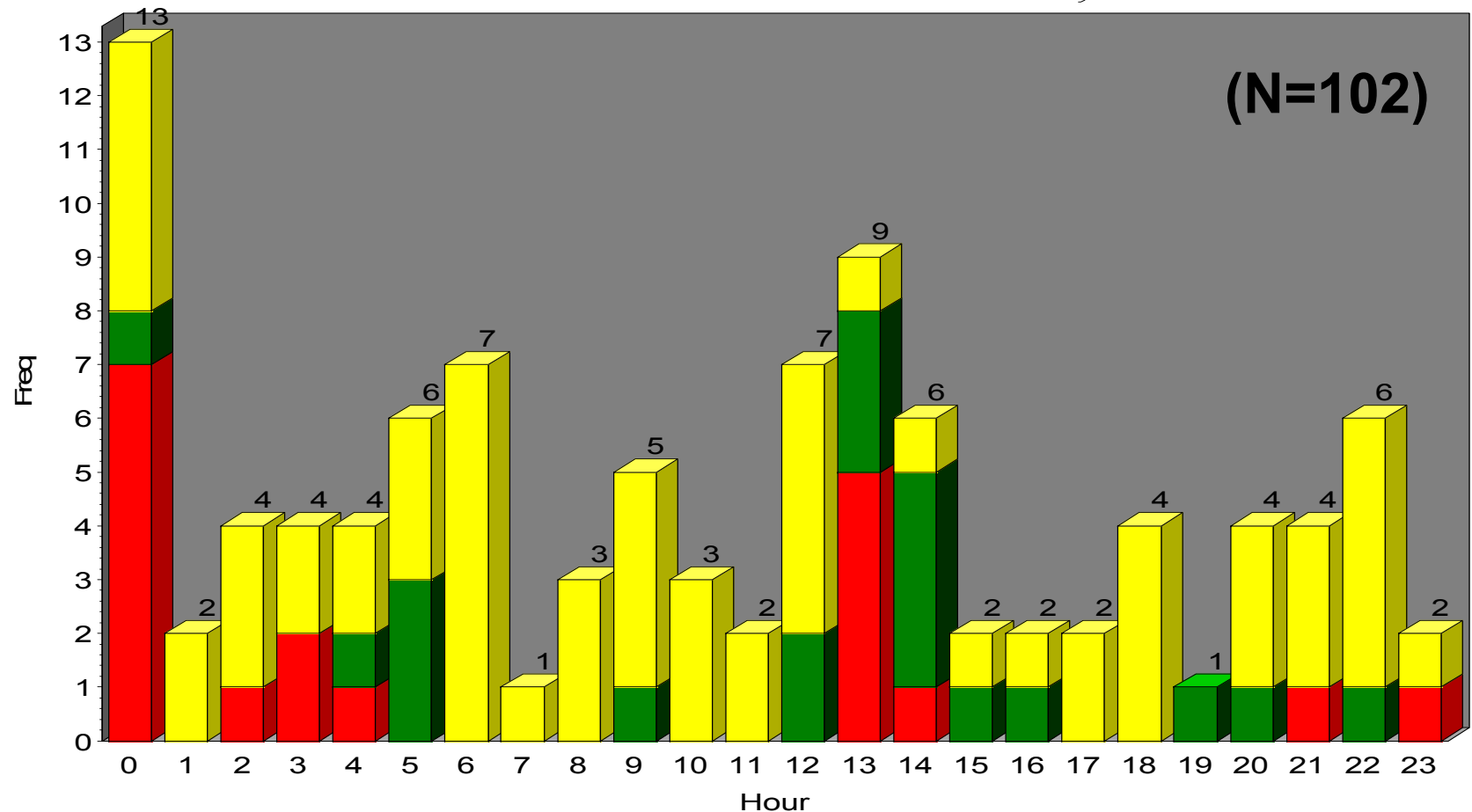


Circadian distribution New onset atrial fibrillation



Circadian distribution Ventricular tachyarrhythmia

Circadian Distribution All V Arrhythmia



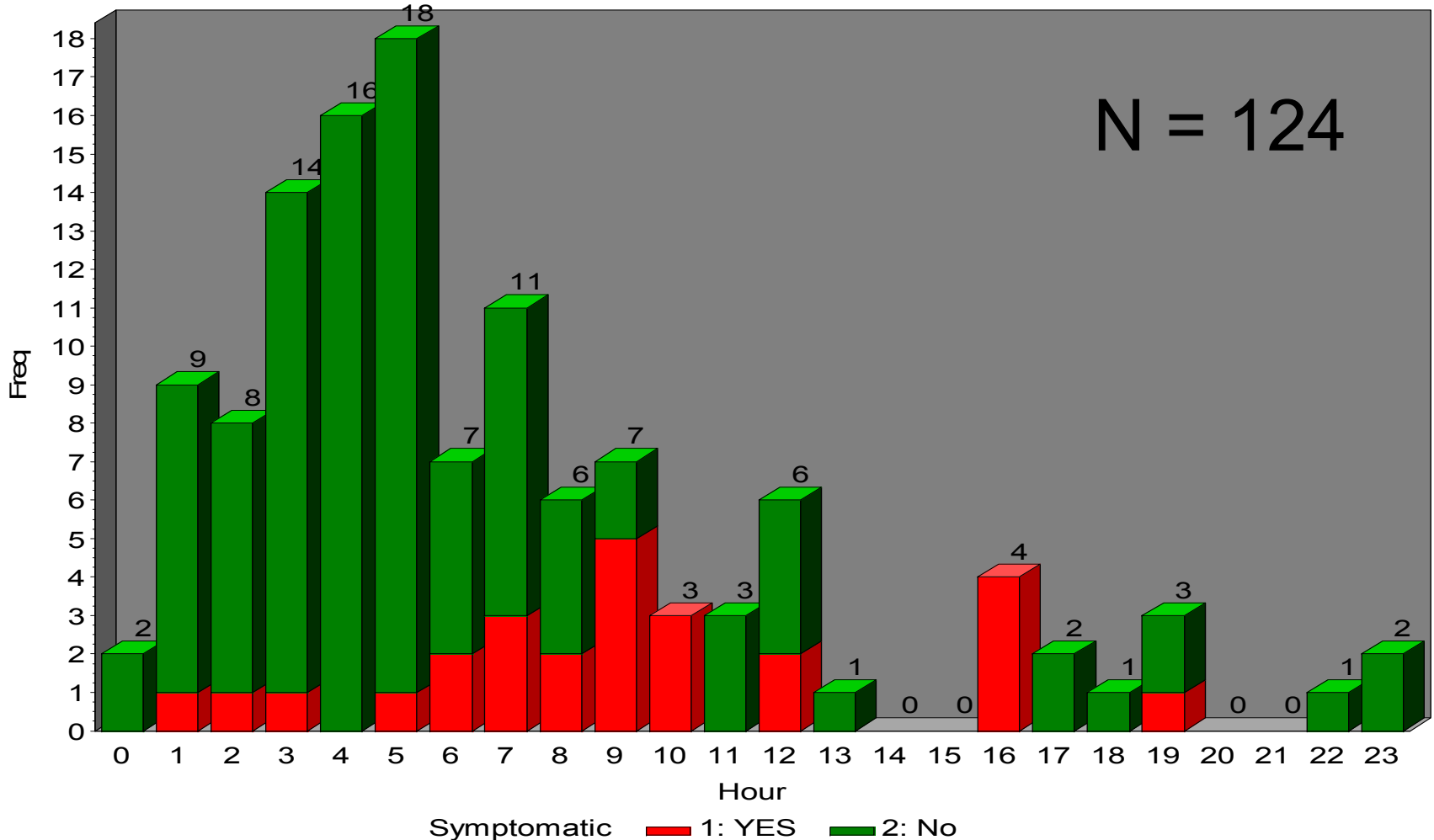
Type V Tachyarrhythmia 1: VF

2: sust VT \geq 30s

3: NSVT \geq 125bpm

Circadian distribution High degree AV block

Circadian Distribution AV block ≥ 8 sec



Limitations of the ILR

- 2⁰-3⁰ SA block with frequency > 30/min
- 2⁰-3⁰ AV block with frequency > 30/min
- AFib with varying RR intervals > 480 ms
- Non sust VT < 16 beats
- VT with CL < 260 ms may be missed
- Undersensing of VF

Limitations of the CARISMA study

- No control group
- Many exclusions
- No follow up of excluded patients

Endpoint Definitions

Composite primary endpoint

1. Sudden cardiac death of arrhythmic origin
2. Resuscitated arrhythmic death
3. Spontaneous, symptomatic, sustained ventricular tachycardia

The arrhythmia should be ECG documented and be likely treatable by an ICD

Secondary endpoints

1. Total mortality
2. Cardiac death